**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION**

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| NICOLE KEITH, RYAN KEITH, JACK R. DODDS, JR., CRYSTALINA R. DODDS, MICHELLE COOPER, and SHANNON MINERICH, on behalf of themselves and all others similarly situated,<br><br>Plaintiffs,<br><br>vs.<br><br>FERRING PHARMACEUTICALS, INC.,<br><br>Defendant. | Civil Action No. 1:15-cv-10381<br><br>Hon. Amy J. St. Eve<br><br>**JURY TRIAL DEMANDED** |

## FIRST AMENDED CLASS ACTION COMPLAINT

Plaintiffs Nicole Keith, Ryan Keith, Jack R. Dodds, Jr., Crystalina R. Dodds, Michelle Cooper and Shannon Minerich ("Plaintiffs"), on behalf of themselves and all persons similarly situated, through their undersigned counsel, allege as follows upon personal knowledge as to facts pertaining to themselves, and upon information and belief (based on the investigation of their counsel) as to all other matters.

## NATURE OF THE ACTION

1. Defendant Ferring Pharmaceuticals, Inc. ("Ferring" or "Defendant") manufactures, warrants, advertises, and sells Bravelle©, the brand name version of the generic drug urofollitropin designed to treat infertility in women. Bravelle stimulates egg maturation and multiple follicular development in women who are able to produce and release eggs. Bravelle is

commonly used in the course of assisted reproductive technology (including, without limitation, in vitro fertilization or "IVF").

2. On or about October 13, 2015, Ferring voluntarily recalled all Bravelle that it sold throughout the United States between March 2014 and October 2015 (the "Recalled Lots") after Ferring's internal quality monitoring revealed that certain lots of the drug did not meet potency specifications, *i.e.*, was sub-potent.

3. The Recalled Lots include the following Lot numbers:

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| H14942A-1 |
| H14942A-2 |
| H1581SA-1 |
| H15815B-1 |
| H15815SMA-1 |
| H16998A-1 |
| H16998SMA-1 |
| K10008A-1 |
| Kl0008A-2 |
| Kl1813A-1 |
| K11813A-2 |
| K11813B-1 |
| K11813C-1 |
| K13031A-1 |
| K13031B-1 |
| K13031B-2 |
| K13503SMA-1 |
| K13503A-1 |
| K13503B-1 |
| Kl3512A-1 |
| K13512A-2 |
| K13921A-1 |
| K13921A-2 |
| K13921B-1 |
| K14616A-1 |
| K14616A-2 |
| K15917A-1 |
| K15917SMA-1 |
| K15917SMA-2 |

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|---|
| K17006AA |
| K18201AA |
| K18202AA |
| L10403AA |
| Ll0403AB |
| L10840AA |
| L10992AA |

4. Specifically, Ferring's stability testing showed a decreased potency in follicle stimulating hormone ("FSH") – a hormone naturally secreted by the anterior pituitary gland that regulates the development, growth, pubertal maturation and reproductive processes of the body and is one of the primary ingredients in Bravelle – resulting in a decreased therapeutic effect and creating the potential for unnecessary over-exposure of patients in establishing an effective dose and, consequently, an increased manifestation of the associated side effects.[1]

5. Plaintiffs bring this action on behalf of themselves and all persons in the United States who purchased Bravelle contained in the Recalled Lots. Before manufacturing, warranting, advertising and/or selling the Recalled Lots of Bravelle, Ferring failed to take appropriate steps to ensure that the Recalled Lots were effective for their intended use and would in fact provide the reproductive health benefits claimed by Ferring. Ferring knew or should have known that the Recalled Lots were not suitable for use and suffered from decreased potency, eliminating or reducing their efficacy in the treatment of infertility.

6. Plaintiffs and the Class, who were injured by their purchase of the Recalled Lots, seek relief for all damages sustained by them that were caused by the Recalled Lots' failure to meet potency specifications, including the out-of-pocket expenditures to purchase the drug, as

[1] The most common side effects of Bravelle include headache, vaginal bleeding, nausea, and hot flashes. A less common but potentially serious side effect is ovarian hyperstimulation syndrome ("OHSS"), a condition in which the ovaries may become swollen and painful due to excessive stimulation.

well as the payments they made to medical providers for fertility treatments utilizing Bravelle, and the associated costs. Plaintiffs seek relief to remedy Ferring's breach of express warranty; breach of implied warranty; unjust enrichment; violation of the Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA"), 815 ILCS 505/2, and the materially similar laws of other states; violation of the Texas Deceptive Trade Practices-Consumer Protection Act, Tex. Bus. & Com. Code §§ 17.41–17.63, *et seq*. ("DTPA"); violation of the Michigan Consumer Protection Act, MCL § 445.901 *et seq*. ("MCPA") and the materially similar laws of other states; violation of the South Dakota Deceptive Trade Practices and Consumer Protection Act, South Dakota Codified Laws §§ 37-24-6 and 37-24-31("SDCL"); and violation of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301, *et seq*. ("MMWA").

## PARTIES

7. Plaintiffs Nicole Keith and Ryan Keith are married and reside in Lansing, Illinois. In or around July 2015, Nicole Keith's sister-in-law, Christina Dorris, began a directed oocyte IVF cycle that included injections of Bravelle. Embryos retrieved from Ms. Dorris at the end of the cycle were then implanted into Mrs. Keith. During the course of treatment, Mr. and Mrs. Keith paid approximately $20,000 to $25,000 in out-of-pocket costs related to the IVF process, including thousands of dollars out-of-pocket to purchase Bravelle. Ultimately, the IVF treatment was not successful and Mrs. Keith did not become pregnant. Due to the significant costs involved in the treatment, Plaintiffs cannot afford to begin another cycle of IVF treatment.

8. Plaintiffs Jack R. Dodds, Jr. and Crystalina R. Dodds are married and reside in Magnolia, Texas. Mrs. Dodds made two purchases of Bravelle during the recall period: the first in April 2014 and the second in July 2014. The Bravelle was used for a total of two cycles of ovarian stimulation and egg retrieval, the first in April 2014 and the second in July 2014.

Plaintiffs spent approximately $3,342 on their purchases of Bravelle, and in excess of $35,000 in related out-of-pocket costs, including such costs as: anesthesiologist fees; medical facility procedure fees; pre-implantation fees; and other medical treatment fees and costs. After two treatment cycles with Bravelle, only three unusable eggs were able to be retrieved from Mrs. Dodds' ovaries. Ultimately, the fertility treatments were not successful and Mrs. Dodds did not become pregnant. Because of the significant costs involved in the treatment, Plaintiffs cannot continue with IVF at this time.

9. Plaintiff Michelle Cooper resides in Gross Pointe, Michigan. Ms. Cooper paid approximately $3,000 for Bravelle to use as part of her treatment leading up to Intrauterine Insemination ("IUI"). Ms. Cooper also incurred an additional $1,000 in related expenses. The Bravelle purchased by Ms. Cooper came from lot number K 11813A-2, a lot that Defendant's own internal testing confirmed to be sub-potent. Ultimately, Ms. Cooper did not become pregnant.

10. Plaintiff Shannon Minerich resides in Marmarth, North Dakota. Mrs. Minerich purchased one cycle of Bravelle in November 2014 in connection with undergoing an IVF cycle and paid approximately $870 out-of-pocket for the Bravelle and approximately $10,000 in additional related out-of-pocket costs. Mrs. Minerich was able to retrieve only two usable eggs. Ultimately, Ms. Minerich's fertility treatment was not successful and she did not become pregnant. At the time Mrs. Minerich purchased the Bravelle contained in the Recalled Lots and underwent the November 2014 IVF cycle, she was a resident of South Dakota.

11. All of the Bravelle purchased by Plaintiffs is part of the Recalled Lots, and all Plaintiffs were damaged as a direct and proximate result of their purchases of Bravelle contained in the Recalled Lots.

12. All of the Plaintiffs would not have purchased Bravelle had they known prior to their purchases that the Bravelle they bought suffered from sub-potency issues, or even that it had the potential to suffer from sub-potency issues. Nor would they have paid the costs associated with the related medical treatment of which Bravelle was an integral part.

13. Ferring is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 100 Interpace Parkway, Parsippany, New Jersey 07054.

## JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction over this class action pursuant to 28 U.S.C. § 1332, as amended by the Class Action Fairness Act of 2005, because the matter in controversy exceeds $5 million, exclusive of interest and costs, and is a class action in which Plaintiffs and some members of the Class are citizens of states different than Defendant. *See* 28 U.S.C. § 1332(d)(2)(A).

15. This Court has personal jurisdiction over Ferring because Ferring conducts substantial business in Illinois and within this District. Ferring has sufficient minimum contacts with the State of Illinois and intentionally avails itself of the consumers and markets within the State of Illinois through the promotion and sale of its products, including Bravelle.

16. Venue properly lies in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the acts giving rise to Plaintiffs' claims occurred in this District and because Ferring is subject to personal jurisdiction within this District.

## FACTUAL ALLEGATIONS

17. Ferring is part of a multinational pharmaceutical company with annual revenues exceeding $1 billion.

18. Ferring describes itself as "a research-driven biopharmaceutical company devoted to commercialization of innovative products in the fields of infertility and reproductive health, gastroenterology, gynecology, orthopedics and urology."

19. In May 2002, the U.S. Food and Drug Administration ("FDA") approved Bravelle, one of Ferring's flagship drugs, for the treatment of infertility.

20. Medications like Bravelle are a regular and normal part of infertility treatments and the in vitro fertilization ("IVF") procedure. These medications are used to prepare the body for treatment and to increase the probability that more healthy eggs are released from the ovaries.

21. Under normal circumstances, ovulation occurs once a month when a ripened egg which is ready to be fertilized is released from the ovaries. For a woman trying to conceive, regular ovulation is incredibly important as this is when a woman is most fertile. If a woman is not ovulating properly, fertility drugs can be prescribed in order to boost the natural system and increase the chances of successful conception.

22. Bravelle is a highly-purified human FSH, one of the most important hormones for inducing the growth of the follicles that produce ova (eggs). FSH is key when it comes to fertility, as it allows a small group of follicles to grow and develop inside the ovary. Each of these follicles contains an egg, so by increasing the body's levels of FSH, the chance of the ovaries releasing a ripe egg for fertilization is increased

23. Because FSH is the main hormone involved in producing mature eggs in the ovaries, FSH treatments result in the development of multiple follicles and increase the quantity of mature egg production in women seeking to become pregnant, making the eggs more likely to be fertilized and increasing the chances of successful conception.

24. As a human FSH, Bravelle is classified as a urofollitropin: injectable hormones that control the reproductive function. Bravelle is administered via either subcutaneous or intramuscular injection. A picture of Bravelle as sold in the United States is below.


25. Because the primary benefits of Bravelle include the development of multiple follicles and stimulation of ovulation and the production of multiple ova via the administration of FSH, it is critical that patients being treated with Bravelle receive appropriate and adequate doses of FSH in order to achieve the intended and specified effects. It is likewise critical that patients being treated with Bravelle receive Bravelle that meets potency specifications, *i.e.*, is not defective.

26. Had Plaintiffs known prior to purchase that the Bravelle they bought suffered from sub-potency issues, or even that it had the potential to suffer from sub-potency issues, they would not have purchased the drug and would not have paid the costs associated with the related medical treatment of which Bravelle was an integral part.

27. Further, had Ferring disclosed to Plaintiffs, the Class, physicians, or the public at large that the Recalled Lots had the potential to suffer from sub-potency issues sooner, Plaintiffs and the Class would not have purchased the drug and would not have paid the costs associated with the related medical treatment of which Bravelle was an integral part.

28. In October 2015, Ferring's internal stability testing began to reveal that certain batches of Bravelle manufactured by Ferring were sub-potent, meaning that they suffered from decreased FSH potency (resulting in a decreased therapeutic effect and, accordingly, unnecessary over-exposure of patients in establishing an effective dose). Consequently, Ferring initiated a voluntary recall of Bravelle in multiple markets including the United States and Canada.

29. Ferring recalled unsold batches of Bravelle directly from pharmacies and sought to recall drugs already sold by sending letters directly to consumers. Subject to the recall were all lots of Bravelle sold in the United States between March 2014 and October 2015. Individual patients who purchased Bravelle are able to contact Ferring and obtain a reimbursement solely for the price of the Bravelle that they purchased once Ferring determines that the Bravelle purchased was from one of the Recalled Lots. Restated, Ferring is offering a reimbursement only for consumers' out-of-pocket expenditures to purchase Bravelle and not for any of the other costs related to the fertility treatments they underwent, the latter of which are often significantly more expensive than the Bravelle itself.

30. While Ferring now claims that only seven (7) of the Recalled Lots exhibit the defect pursuant to its own internal testing, it nevertheless recalled *thirty-two* (32) Recalled Lots of Bravelle. Voluntarily incurring the costs of recalling the 32 lots suggests a strong inference that Ferring knew or suspected that all of the 32 lots were sub-potent or had the potential to be sub-potent.

31. Upon information and belief, all of the Recalled Lots were defective and Ferring knew or should have known that the Recalled Lots were defective. The Recalled Lots should not have been sold and used by women who were paying huge sums of money for medical treatments so that they could attempt to become pregnant.

32. The Bravelle purchased by all Plaintiffs was included in the Recalled Lots. Shortly after the recall, in October 2015, each of the Plaintiffs received letters from Ferring informing them of the reduced potency issue and recall, stating that "[i]f you purchased BRAVELLE in the U.S. between March 27, 2014 and October 15, 2015 you may be eligible for reimbursement of your out-of-pocket costs for BRAVELLE." *See* Letter attached hereto as **Exhibit 1** (emphasis in original). As expressly stated, the reimbursement offer applies only to out-of-pocket costs and does not include payment for the full cost of IVF, IUI, or other medical fertility treatments that utilized and relied upon Bravelle to stimulate egg production.

33. Ferring's website continues to market and advertise Bravelle to consumers but contains no reference whatsoever to the reduced potency problems or the recall and provides no method for consumers to determine whether they purchased and used Bravelle that is part of the Recalled Lots.

34. As set forth above, all of the Plaintiffs used and were damaged by Ferring's Bravelle that was sold as part of the Recalled Lots.

## CLASS ALLEGATIONS

35. Plaintiffs bring Counts I, II, III, and VIII below, individually and as a class action, pursuant to FED. R. CIV. P. 23(a), 23(b)(2) and/or 23(b)(3), on behalf of a nationwide class of consumers who purchased Bravelle contained in the Recalled Lots, as defined below:

> All persons or entities in the United States who purchased Bravelle contained in the Recalled Lots (the "Nationwide Class"). Excluded from the Nationwide Class

> are Defendant and any person, firm, trust, corporation, or other entity related to or affiliated with Defendant.

36. Alternatively, or in addition to the Nationwide Class claims, Plaintiffs Nicole and Ryan Keith bring Counts I, II, III, IV and VIII under FED. R. CIV. P. 23(a), 23(b)(2) and/or 23(b)(3) on behalf of themselves and all similarly situated individuals and entities residing in Illinois and other states where the laws are materially similar to those of Illinois (the "Multistate Class"). The Multistate Class consists of:

> All persons or entities in Illinois, California, Florida, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, New York, and Washington who purchased Bravelle contained in the Recalled Lots. Excluded from the Multistate Class are Defendant and any person, firm, trust, corporation, or other entity related to or affiliated with Defendant.

37. Alternatively, or in addition to the Nationwide Class and Multistate Class claims, Plaintiffs Nicole Keith and Ryan Keith bring Counts I, II, III, IV and VIII under FED. R. CIV. P. 23(a), 23(b)(2) and/or 23(b)(3) on behalf of themselves and all similarly situated individuals and entities residing in Illinois (the "Illinois Class"). The Illinois Class consists of:

> All persons or entities in Illinois who purchased Bravelle contained in the Recalled Lots. Excluded from the Class are Defendant and any person, firm, trust, corporation, or other entity related to or affiliated with Defendant.

38. Alternatively, or in addition to the Nationwide Class and Multistate Class claims, Plaintiffs Jack R. Dodds, Jr. and Crystalina R. Dodds bring Counts I, II, III, V, and VIII under FED. R. CIV. P. 23(a), 23(b)(2) and/or 23(b)(3) on behalf of themselves and all similarly situated individuals and entities residing in Texas (the "Texas Class"). The Texas Class consists of:

> All persons or entities in Texas who purchased Bravelle contained in the Recalled Lots. Excluded from the Class are Defendant and any person, firm, trust, corporation, or other entity related to or affiliated with Defendant.

39. Alternatively, or in addition to the Nationwide Class and Multistate Class claims, Plaintiff Michelle Cooper brings Counts I, II, III, VI, and VIII under FED. R. CIV. P. 23(a),

23(b)(2) and/or 23(b)(3) on behalf of herself and all similarly situated individuals and entities residing in Michigan (the "Michigan Class"). The Michigan Class consists of:

> All persons or entities in Michigan who purchased Bravelle contained in the Recalled Lots. Excluded from the Class are Defendant and any person, firm, trust, corporation, or other entity related to or affiliated with Defendant.

Mrs. Cooper also brings Counts I, II, III, VI, and VIII on behalf of the Multistate Class.

40. Alternatively, or in addition to the Nationwide Class and Multistate Class claims, Plaintiff Shannon Minerich brings Counts I, II, III, VII, and VIII under FED. R. CIV. P. 23(a), 23(b)(2) and/or 23(b)(3) on behalf of herself and all similarly situated individuals and entities residing in South Dakota (the "South Dakota Class"). The South Dakota Class consists of:

> All persons or entities in South Dakota who purchased Bravelle contained in the Recalled Lots. Excluded from the Class are Defendant and any person, firm, trust, corporation, or other entity related to or affiliated with Defendant.

41. The Nationwide, Multistate, Illinois, Texas, Michigan, and South Dakota Classes are collectively referenced herein as the "Class."

42. Plaintiffs reserve the right to redefine the Class prior to class certification.

43. The rights of each member of the Class were violated in a similar fashion based upon Ferring's uniform actions.

44. This action has been brought and may be properly maintained as a class action for the following reasons:

a. Numerosity: Members of the Class are so numerous that their individual joinder is impracticable. Plaintiffs are informed and believe that the proposed Class contains thousands of individuals or entities that purchased the Recalled Lots, either out-of-pocket or via co-payments made to their health care providers for fertility treatments utilizing Bravelle. The

Class is therefore sufficiently numerous to make joinder impracticable, if not impossible. The precise number of Class members is unknown to Plaintiffs at this time.

b. Existence and Predominance of Commons Questions of Fact and Law: Common questions of law and fact exist as to all members of the Class. These questions predominate over any questions affecting individual Class members. These common legal and factual questions include, but are not limited to, the following:

i. Whether the Bravelle contained in the Recalled Lots met the potency specifications warranted and claimed by Ferring;

ii. Whether the Recalled Lots were merchantable goods at the time of sale;

iii. Whether the Recalled Lots were fit for their intended purpose;

iv. Whether Defendant made fraudulent, false, deceptive, and/or misleading statements in connection with the sale of the Recalled Lots;

v. Whether Defendant omitted material information when it sold the Recalled Lots and the date on which Defendant knew or should have known of the sub-potency issues with the Recalled Lots;

vi. Whether Defendant's recall notice to consumers was timely and/or sufficient;

vii. Whether Defendant breached the terms of its express warranty.

viii. The appropriate nature of class-wide equitable relief, and;

ix. The appropriate measurement of restitution and/or measure of damages to award to Plaintiffs and members of the Class.

These and other questions of law or fact which are common to the members of the Class predominate over any questions affecting only individual members of the Class.

c. Typicality: Plaintiffs' claims are typical of the claims of the Class since Plaintiffs and all members of the putative Class purchased and used Bravelle contained in the Recalled Lots. Furthermore, Plaintiffs and all members of the Class sustained monetary and economic injuries arising out of Defendant' wrongful conduct by, *inter alia,* purchasing the Recalled Lots for use in their fertility treatment (either out-of-pocket or via co-payments made to their pharmacist or healthcare professionals) notwithstanding the decreased potency and the resultant risk of overexposure and manifestation of associated side effects. Had this material information been disclosed to Plaintiffs and the Class members, they would not have purchased the Bravelle contained in the Recalled Lots. Plaintiffs are advancing the same claims and legal theories on behalf of themselves and all absent Class members.

d. Adequacy: Plaintiffs are adequate representatives of the Class because their interests do not conflict with the interests of the Class that they seek to represent; they have retained counsel competent and highly experienced in complex class action litigation and they intend to prosecute this action vigorously. The interests of the Class will be fairly and adequately protected by Plaintiffs and their counsel.

e. Superiority: A class action is superior to other available means of fair and efficient adjudication of the claims of Plaintiffs and members of the Class. The injury suffered by each individual Class member is relatively small in comparison to the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Defendant's conduct. It would be virtually impossible for members of the Class to individually and effectively redress the wrongs done to them. Even if the members of the Class could afford such

individual litigation, the court system could not. Individualized litigation presents a potential for inconsistent or contradictory judgments. Individualized litigation also increases the delay and expense to all parties, and to the court system, presented by the complex legal and factual issues of the case. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, an economy of scale, and comprehensive supervision by a single court.

f. Ascertainability: Class members are readily ascertainable, and can be identified by Defendant's records.

## CAUSES OF ACTION

### COUNT I
### BREACH OF EXPRESS WARRANTY
### (On Behalf of the Nationwide Class, the Multistate Class, the Illinois Class, the Texas Class, the Michigan Class, and the South Dakota Class)

45. Plaintiffs and the Class incorporate by reference paragraphs 1-44 as though fully set forth herein.

46. Plaintiffs bring this cause of action on behalf of themselves and on behalf of the members of the Class against Defendant.

47. Defendant's Recalled Lots are goods and thus Plaintiffs' and the Class's breach of express warranty claim is governed by the Uniform Commercial Code.

48. Defendant's Recalled Lots contained an express warranty with every purchase. Namely, each package of Bravelle comes with a Patient Information form (attached hereto as **Exhibit 2**). Ferring warranted that the Recalled Lots contained FSH in sufficient amount and with sufficient potency to treat women who need help developing and releasing eggs as well as those with healthy ovaries to make multiple eggs as part of an ART Cycle. Moreover, the Prescribing Information for Bravelle warrants that the medication "contain[s] 82.5 International

Units of FSH, to deliver 75 International Units FSH after reconstituting." As described above, quality monitoring revealed reduced FSH potency in the Recalled Lots.

49. Such warranty became part of the basis of the transaction between Plaintiffs and the putative Class and Defendant.

50. Defendant breached its express warranties because the Recalled Lots were not as promised and did not conform to these promises, affirmations, or representations.

51. As a result of Defendant's breach, Plaintiffs and the Class have suffered damages including, but not limited to, the amounts spent to purchase Bravelle for use in fertility treatment as well as the additional amounts paid to medical providers for fertility treatments utilizing Bravelle.

## COUNT II
## BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
**(On Behalf of the Nationwide Class, the Multistate Class, the Illinois Class, the Texas Class, the Michigan Class, and the South Dakota Class)**

52. Plaintiffs and the Class incorporate by reference paragraphs 1-44 as though fully set forth herein.

53. Plaintiffs bring this cause of action on behalf of themselves and on behalf of the members of the Class against Defendant.

54. At all times mentioned herein, Defendant manufactured and/or supplied the Recalled Lots and, prior to the time the Recalled Lots were purchased by Plaintiffs and the Class, Defendant impliedly warranted to Plaintiffs and their health care providers that the Recalled Lots were of merchantable quality and fit for the use for which they were intended.

55. Plaintiffs and their health care providers relied on the skill and judgment of Defendant in using the Recalled Lots.

56. The Recalled Lots were unfit for their intended use and were not of merchantable quality, as warranted by Defendant, because they did meet the product specifications regarding FSH potency. As a result, the Recalled Lots fail to perform when put to their intended use.

57. Defendant breached the implied warranty of merchantability as the Recalled Lots were not of a merchantable quality at the time of sale.

58. As a direct and proximate result of the breach of said warranties, Plaintiffs and the putative Class suffered and will continue to suffer losses and damages as alleged herein in an amount to be determined at trial.

59. Plaintiffs and Class members have complied with all obligations under the warranty, or otherwise have been excused from performance of said obligations as a result of Defendant's conduct described herein.

## COUNT III
## UNJUST ENRICHMENT
**(On Behalf of the Nationwide Class, the Multistate Class, the Illinois Class, the Texas Class, the Michigan Class, and the South Dakota Class)**

60. Plaintiffs and the Class incorporate by reference paragraphs 1-44 as though fully set forth herein.

61. Plaintiffs and Class members conferred a tangible economic benefit upon Defendant by purchasing the Recalled Lots. Plaintiffs and Class members would not have purchased the Recalled Lots had they known that those Recalled Lots would not perform as warranted.

62. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Class members.

63. Defendant's retention of the benefit conferred upon them by Plaintiffs and members of the Class would be unjust and inequitable.

**COUNT IV**
**VIOLATION OF THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT AND MATERIALLY SIMILAR STATE LAWS**
**(On Behalf of the Multistate Class or, Alternatively, the Illinois Class)**

64. Plaintiffs and the Class incorporate by reference paragraphs 1-44 above as if fully set forth herein.

65. Plaintiffs Nicole and Ryan Keith bring this Count individually and on behalf of the other members of the Multistate and Illinois Classes defined above.

66. The ICFA prohibits unfair or deceptive acts or practices in connection with any trade or commerce, including, among other things, "the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact,…whether any person has in fact been misled, deceived, or damaged thereby." The Act also prohibits suppliers from representing that their goods are of a particular quality or grade that they are not.

67. In violation of the ICFA, Ferring knew but failed to disclose the material fact that the Recalled Lots were defective in that they did not meet the potency standards advertised and warranted by Ferring.

68. Ferring's failure to publicly disclose to doctors and consumers that Bravelle was potentially subject to potency issues affected consumers and their physicians. Absent such fraud, Plaintiffs and the Class would not have purchased the drug.

69. None of Ferring's promotional materials or labels disclosed the fact that Bravelle suffered from potency problems or had the potential to suffer from potency problems. Nor did

any of these materials provide any warning concerning the potential adverse health effects associated with increased doses of Bravelle necessitated because of potency issues.

70. As a direct result of Ferring's deception, Plaintiffs and the Class were deceived into purchasing Bravelle and spending money on costs incidental to the administration of Bravelle. In exchange for this money, Plaintiffs and the Class received something other than what was represented: a potentially ineffective product they did not seek.

71. Because of Ferring's deceptive acts and practices, Plaintiffs and the Class were misled into purchasing Bravelle, thereby resulting in injury in fact and a loss of money or property resulting from Ferring's conduct. Had warnings concerning sub-potency issues in Bravelle been given by Defendant earlier– which they were not – Plaintiffs and the Class would not have purchased Bravelle and exposed themselves to the potential health problems associated with the drug.

72. Ferring's deception directly caused an overvaluation of Bravelle and resulted in payments for Bravelle that would not have occurred otherwise.

73. Furthermore, Ferring violated the Illinois Uniform Deceptive Trade Practices Act 815 ILCS 510/2, which broadly proscribes various deceptive trade practices. Ferring specifically violated 815 ILCS 510/2(a)(5), by representing that the Bravelle in the Recalled Lots had characteristics and quantities that they do not have and 815 ILCS 510/2(a)(7) by representing that the Bravelle in the Recalled Lots was of a particular standard, quality, or grade when it was not.

74. Ferring's misrepresentations regarding the Recalled Lots constitute unfair competition or unfair, unconscionable, deceptive, fraudulent or unlawful acts or business practices in violation of the Act and the following State consumer protection statutes, which are

materially similar to the ICFA: California (Cal. Bus. & Prof. Code § 17200, *et seq*. and Cal. Civil Code § 1750, *et seq*.); Florida (Fla. Stat. § 501.201, *et seq*.); Massachusetts (Mass. Gen. Laws Ch. 93A, *et seq*.); Michigan (Mich. Comp. Laws § 445.901, *et seq*.); Minnesota (Minn. Stat. § 325F.67, *et seq*.); Missouri (Mo. Rev. Stat. § 407.010, *et seq*.); New Jersey (N.J. Stat. § 56:8-1, *et seq*.); New York (N.Y. Gen. Bus. Law § 349, *et seq*.); and Washington (Wash. Rev. Code § 19.86.010, *et seq.)*.

75. Ferring's deceptive or unfair practices took place in the course of trade and commerce.

76. Ferring intended for Plaintiffs and the Classes to rely on these deceptive and unfair practices when Plaintiffs and the Class purchased the Recalled Lots.

77. Plaintiffs and the Class have suffered injuries in fact and actual damages, including financial losses, due to Ferring's violations of the ICFA and the materially similar consumer fraud laws of other states, as alleged herein. These injuries are of the type that the above State consumer protection statutes were designed to prevent and are the direct and proximate result of Ferring's unlawful conduct.

## COUNT V
## VIOLATION OF THE TEXAS DECEPTIVE TRADE PRACTICES-CONSUMER PROTECTION ACT
## (On Behalf of the Texas Class)

78. Plaintiffs and the Class incorporate by reference paragraphs 1-44 above as though fully set forth herein.

79. Plaintiffs Jack R. Dodds, Jr. and Crystalina R. Dodds bring this claim pursuant to the DTPA.

80. The purpose of the DTPA is to protect consumers from false, misleading, or deceptive business practices, unconscionable actions, and breaches of warranty. TEX. BUS. &

COM. CODE § 17.44(a). A claim under the DTPA may be brought in conjunction with many common-law causes of action, including breach of warranty, misrepresentation, and negligence. *PPG Indus. v. JMB/Houston Ctrs. Partners*, 146 S.W.3d 79, 89 (Tex. 2004).

81. Plaintiffs and the Class members are "consumers" as defined in § 17.45(4) of the DTPA.

82. In violation of the DTPA, Ferring knew but failed to disclose the material fact that the Recalled Lots were defective in that they did not meet the potency standards advertised and warranted by Ferring.

83. Ferring's failure to publicly disclose to doctors and consumers that Bravelle was potentially subject to potency issues affected consumers and their physicians. Absent such fraud, Plaintiffs and the Class would not have purchased the drug.

84. None of Ferring's promotional materials or labels disclosed the fact that Bravelle suffered from potency problems or had the potential to suffer from potency problems. Nor did any of these materials provide any warning concerning the potential adverse health effects associated with increased doses of Bravelle necessitated because of potency issues.

85. As a direct result of Ferring's deception, Plaintiffs and the Class were deceived into purchasing Bravelle and spending money on costs incidental to the administration of Bravelle. In exchange for this money, Plaintiffs and the Class received something other than what was represented: a potentially ineffective product they did not seek.

86. Because of Ferring's deceptive acts and practices, Plaintiffs and the Class were misled into purchasing Bravelle, thereby resulting in injury in fact and a loss of money or property resulting from Ferring's conduct. Had warnings concerning sub-potency issues in Bravelle been given by Defendant – which they were not – Plaintiffs and the Class would not

have purchased Bravelle and exposed themselves to the potential health problems associated with the drug.

87. Ferring's deception directly caused an overvaluation of Bravelle and resulted in payments for Bravelle that would not have occurred otherwise.

88. Ferring's misrepresentations concerning the Recalled Lots constitute false, misleading, or deceptive business practices, unconscionable actions, and breaches of warranty in violation of the DTPA

89. Plaintiffs and the Class relied on Ferring's misrepresentations to their detriment.

90. Ferring's violations of the DTPA include:

(a) TEX. BUS. & COM. CODE § 17.50(a)(1) – the use or employment of false, misleading, or deceptive acts or practices that were detrimentally relied upon by Plaintiff as defined in:

(i) TEX. BUS. & COM. CODE § 17.46(b)(5) – representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person has a sponsorship, approval, status, affiliation, or connection which he does not.

(ii) TEX. BUS. & COM. CODE § 17.46(b)(7) – representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another.

(iii) TEX. BUS. & COM. CODE § 17.46(b)(9) – advertising goods or services with intent not to sell them as advertised.

(iv) TEX. BUS. & COM. CODE § 17.46(b)(24) – failing to disclose information concerning goods or services which was known at the time of the transaction if such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed.

(b) TEX. BUS. & COM. CODE § 17.50(a)(2) – breach of express warranty, as defined in TEX. BUS. & COM. CODE § 2.313; and

(c) TEX. BUS. & COM. CODE § 17.50(a)(2) – breach of the implied warranty of merchantability as defined in TEX. BUS. & COM. CODE § 2.314.

91. The limited remedies in Ferring's warranty failed of their essential purpose and deprived Plaintiffs and the Class of the substantial value of the bargain because Ferring did not correct the defective product within a reasonable time. TEX. BUS. & COM. CODE § 2.719. Additionally, the exclusion of consequential damages is unconscionable.

92. Plaintiffs further contend that Ferring's violations of the DTPA were committed knowingly and intentionally as those terms are defined in § 17.45(9) and § 17.45(13) of the DTPA.

93. Ferring's deceptive or unfair practices took place in the course of trade and commerce.

94. Ferring intended for Plaintiffs and the Class to rely on these deceptive and unfair practices when Plaintiffs purchased the Recalled Lots.

95. Plaintiffs and the Class have suffered injuries in fact and actual damages, including financial losses.

96. These injuries are of the type the DTPA was designed to prevent and are the direct and proximate result of Ferring's unlawful conduct.

## COUNT VI
## VIOLATION OF THE MICHIGAN CONSUMER PROTECTION ACT
## (On Behalf of the Multistate Class or, Alternatively, the Michigan Class)

97. Plaintiffs and the Class incorporate by reference paragraphs 1-44 above as if fully set forth herein.

98. Plaintiff Michelle Cooper brings this Count individually and on behalf of the other members of the Multistate and Michigan Classes defined above.

99. The MCPA prohibits unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce.

100. In violation of the MCPA, Ferring knew but failed to disclose the material fact that the Recalled Lots were defective in that they did not meet the potency standards advertised and warranted by Ferring.

101. Ferring's failure to publicly disclose to doctors and consumers that Bravelle was potentially subject to potency issues affected consumers and their physicians. Absent such fraud, Plaintiff Cooper and the Class would not have purchased the drug.

102. None of Ferring's promotional materials or labels disclosed the fact that Bravelle suffered from potency problems or had the potential to suffer from potency problems. Nor did any of these materials provide any warning concerning the potential adverse health effects associated with increased doses of Bravelle necessitated because of potency issues.

103. As a direct result of Ferring's deception, Plaintiff Cooper and the Class were deceived into purchasing Bravelle and spending money on costs incidental to the administration of Bravelle. In exchange for this money, Plaintiff Cooper and the Class received something other than what was represented: a potentially ineffective product they did not seek.

104. Because of Ferring's deceptive acts and practices, Plaintiff Cooper and the Class were misled into purchasing Bravelle, thereby resulting in injury in fact and a loss of money or property resulting from Ferring's conduct. Had warnings concerning sub-potency issues in Bravelle been given by Defendant – which they were not – Plaintiff Cooper and the Class would

not have purchased Bravelle and exposed themselves to the potential health problems associated with the drug.

105. Ferring's deception directly caused an overvaluation of Bravelle and resulted in payments for Bravelle that would not have occurred otherwise.

106. Furthermore, Ferring violated MCLS § 445.903(c) by representing that the Bravelle in the Recalled Lots had characteristics and quantities that it does not have and MCLS § 445.903(e) by representing that the Bravelle in the Recalled Lots was of a particular standard, quality, or grade when it was not.

107. Ferring's misrepresentations regarding the Recalled Lots constitute unfair competition or unfair, unconscionable, deceptive, fraudulent or unlawful acts or business practices in violation of the Act and the following State consumer protection statutes, which are materially similar to the MCPA: California (Cal. Bus. & Prof. Code § 17200, *et seq*. and Cal. Civil Code § 1750, *et seq*.); Florida (Fla. Stat. § 501.201, *et seq*.); Illinois (815 ILCS § 505/2, *et seq*.); Massachusetts (Mass. Gen. Laws Ch. 93A, *et seq*.); Minnesota (Minn. Stat. § 325F.67, *et seq*.); Missouri (Mo. Rev. Stat. § 407.010, *et seq.*); New Jersey (N.J. Stat. § 56:8-1, *et seq*.); New York (N.Y. Gen. Bus. Law § 349, *et seq*.); and Washington (Wash. Rev. Code § 19.86.010, *et seq.).*

108. Ferring's deceptive or unfair practices took place in the course of trade and commerce.

109. Ferring intended for Plaintiff Cooper and the Classes to rely on these deceptive and unfair practices when Plaintiff Cooper and the Class purchased the Recalled Lots.

110. Plaintiff Cooper and the Class have suffered injuries in fact and actual damages, including financial losses, due to Ferring's violations of the MCPA and the materially similar

consumer fraud laws of other states, as alleged herein. These injuries are of the type that the above State consumer protection statutes were designed to prevent and are the direct and proximate result of Ferring's unlawful conduct.

**COUNT VII**
**VIOLATION OF THE SOUTH DAKOTA DECEPTIVE TRADE PRACTICES AND CONSUMER PROTECTION ACT**
**(On Behalf of the South Dakota Class)**

111. Plaintiffs and the Class incorporate by reference paragraphs 1-44 above as if fully set forth herein.

112. Plaintiff Shannon Minerich brings this Count individually and on behalf of the other members of the South Dakota Class defined above.

113. It is a violation of the SDCL for any person to knowingly act, use, or employ any deceptive act or practice, fraud, false pretense, false promises, or misrepresentation or to conceal, suppress, or omit any material fact in connection with the sale or advertisement of any merchandise, regardless of whether any person has in fact been misled, deceived, or damaged thereby.

114. Ferring is a "person" within the meaning of the SDCL.

115. The Bravelle Plaintiff Minerich purchased is "merchandise" within the meaning of the SDCL.

116. In violation of the SDCL, Ferring knew but failed to disclose the material fact that the Recalled Lots were defective in that they did not meet the potency standards advertised and warranted by Ferring.

117. Ferring's failure to publicly disclose to doctors and consumers that Bravelle was potentially subject to potency issues affected consumers and their physicians. Absent such fraud, Plaintiff Minerich and the Class would not have purchased the drug.

118. None of Ferring's promotional materials or labels disclosed the fact that Bravelle suffered from potency problems or had the potential to suffer from potency problems. Nor did any of these materials provide any warning concerning the potential adverse health effects associated with increased doses of Bravelle necessitated because of potency issues.

119. As a direct result of Ferring's deception, Plaintiff Minerich and the Class were deceived into purchasing Bravelle and spending money on costs incidental to the administration of Bravelle. In exchange for this money, Plaintiff Minerich and the Class received something other than what was represented: a potentially ineffective product they did not seek.

120. Because of Ferring's deceptive acts and practices, Plaintiff Minerich and the Class were misled into purchasing Bravelle, thereby resulting in injury in fact and a loss of money or property resulting from Ferring's conduct. Had warnings concerning sub-potency issues in Bravelle been given by Defendant – which they were not – Plaintiff Minerich and the Class would not have purchased Bravelle and exposed themselves to the potential health problems associated with the drug.

121. Ferring's deception directly caused an overvaluation of Bravelle and resulted in payments for Bravelle that would not have occurred otherwise.

122. Ferring's misrepresentations regarding the Recalled Lots constitute deceptive acts or practices in violation of the SDCL.

123. Ferring's deceptive or unfair practices took place in the course of trade and commerce.

124. Ferring intended for Plaintiff Minerich and the Class to rely on these deceptive and unfair practices when Plaintiff Minerich and the Class purchased the Recalled Lots.

125. Plaintiffs and the Class have suffered injuries in fact and actual damages, including financial losses, due to Ferring's violations of the SDCL, as alleged herein. These injuries are of the type that the SDCL is designed to prevent and are the direct and proximate result of Ferring's unlawful conduct.

## COUNT VIII
## VIOLATION OF THE MAGNUSON-MOSS WARRANTY ACT
**(On Behalf of the Nationwide Class, the Multistate Class, the Illinois Class, the Texas Class, the Michigan Class, and the South Dakota Class)**

126. Plaintiffs adopt and incorporate by reference paragraphs 1-44 above as if fully set forth herein.

127. Plaintiffs bring this cause of action individually and on behalf of the members of the Class against Ferring.

128. Bravelle is a consumer product as defined in 15 U.S.C. § 2301(1).

129. Plaintiffs and the Class members are consumers as defined in 15 U.S.C. § 2301(3).

130. Ferring is a supplier and warrantor as defined in 15 U.S.C. § 2301(4) and (5).

131. In connection with the sale of Bravelle, Ferring issued written warranties as defined in 15 U.S.C. § 2301(6) by making the express representations and warranties described herein.

132. The Recalled Lots do not conform to the express warranties regarding Bravelle's potency because each of the express warranties is false and misleading.

133. By reason of Ferring's breach of warranties, Ferring violated the statutory rights due to Plaintiffs and the Class members pursuant to the MMWA, thereby damaging Plaintiffs and the Class members.

134. Affording Ferring a reasonable opportunity to cure its breach of written warranties would be unnecessary and futile here. At the time Ferring sold the Recalled Lots, Ferring should have known, or was reckless in not knowing, of its misrepresentations concerning the potency of the Bravelle contained in the Recalled Lots but nonetheless failed to rectify the situation and/or disclose the defect. Under these circumstances, the remedies available under any informal settlement procedure would be inadequate and any requirements that Plaintiffs resort to an informal dispute resolution procedure and/or afford Ferring a reasonable opportunity to cure its breach of warranties are excused and thereby deemed satisfied.

135. Plaintiffs and the Class members were injured as a direct and proximate result of Ferring's breach because they would not have purchased Bravelle from the Recalled Lots if the true facts had been known.

## PRAYER FOR RELIEF

**WHEREFORE**, Plaintiffs request, on behalf of themselves and members of the Class, that this Court:

A. determine that the claims alleged herein may be maintained as a class action under Rule 23(a), (b)(2), and/or (b)(3) of the Federal Rules of Civil Procedure, and issue an order certifying the Class as defined above and designating Plaintiffs' counsel as counsel for the Class;

B. award all actual, general, special, incidental, statutory, treble or other multiple, punitive and consequential damages to which Plaintiffs and Class members are entitled;

C. award pre-judgment and post-judgment interest on such monetary relief;

D. award reasonable attorneys' fees and costs; and grant such further and other relief that this Court deems appropriate.

## JURY DEMAND

Plaintiffs, on behalf of themselves and the Class, demand a trial by jury on all issues so triable.

Dated: March 9, 2016

**LITE DEPALMA GREENBERG, LLC**

By: */s/ Katrina Carroll*

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***Counsel for Plaintiffs and the Putative Class***

FERRING
PHARMACEUTICALS

Dear Valued Patient,

During routine quality monitoring, Ferring Pharmaceuticals Inc. recently determined that certain lots of BRAVELLE® (urofollitropin for injection, purified) did not meet potency requirements through the expiration date. To ensure that all of its products adhere to the highest quality standards, Ferring decided to voluntarily remove all remaining lots of BRAVELLE from the U.S. market.

To further demonstrate its commitment to the patients who use its products, Ferring has established a reimbursement program for patients who purchased the affected BRAVELLE in the U.S. If you purchased BRAVELLE in the U.S. between March 27, 2014 and October 15, 2015 you may be eligible for reimbursement of your out-of-pocket costs for BRAVELLE. To determine if you are eligible for reimbursement, please contact us at **1-877-650-3482** Monday through Friday between the hours of 8AM – 5PM EST.

Representatives will be able to provide you with additional information regarding the reimbursement program and answer questions related to the BRAVELLE recall.

We thank you for your patience during this time.

Sincerely,

Ferring Pharmaceuticals

# Patient Information

**BRAVELLE® (brä-vel)**
(urofollitropin for injection, purified)
for subcutaneous use

Read this Patient Information before you start using BRAVELLE® and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

## What is BRAVELLE®?

BRAVELLE® is a prescription medicine that contains follicle stimulating hormone (FSH). BRAVELLE® is used to treat women:

- who need help developing and releasing eggs (ovulating) and have already received a medicine to control their pituitary gland
- with healthy ovaries so they can make multiple (more than 1) eggs as part of an Assisted Reproductive Technology (ART) Cycle

## Who should not use BRAVELLE®?

**Do not use BRAVELLE® if you:**

- are allergic to urofollitropin or any of the ingredients in BRAVELLE®. See the end of this leaflet for a complete list of ingredients in BRAVELLE®.
- have ovaries that no longer make eggs (primary ovarian failure)
- are pregnant or think you may be pregnant. If BRAVELLE® is taken while you are pregnant, it may harm your baby,
- have problems with your thyroid gland or adrenal gland or pituitary gland that are not controlled by taking medicine
- have a tumor in your female organs, including your ovaries, breast, or uterus that may get worse with high levels of estrogen
- have a tumor of your pituitary gland or hypothalamus
- have abnormal bleeding from your uterus or vagina and the cause is not known
- have ovarian cysts or enlarged ovaries, not due to a problem called polycystic ovary syndrome (PCOS)

## What should I tell my healthcare provider before using BRAVELLE®?

**Before using BRAVELLE®, tell your healthcare provider if you:**

- have been told by a healthcare provider that you are at an increased risk for blood clots (thrombosis)
- have ever had a blood clot (thrombosis), or anyone in your family has ever had a blood clot
- had stomach (abdominal) surgery
- had twisting of your ovary (ovarian torsion)
- had or have a cyst in your ovary
- have any other medical conditions
- are breast feeding or plan to breast feed. It is not known if BRAVELLE® passes into your breast milk. You and your healthcare provider should decide if you will use BRAVELLE® or breastfeed. You should not do both.

**Tell your healthcare provider all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

**How should I use BRAVELLE®?**

- Read the **Instructions for Use** at the end of this Patient Information about the right way to use BRAVELLE® or BRAVELLE® mixed with MENOPUR®.
- Use BRAVELLE® exactly as your healthcare provider tells you to use it.
- Your healthcare provider will tell you how much BRAVELLE® to use and when to use it.
- Your healthcare provider may change your dose of BRAVELLE® if needed.
- If you miss a dose of BRAVELLE®, call your healthcare provider right away. **Do not** double the amount of BRAVELLE® you are taking.
- You may need more than 1 vial of BRAVELLE® for your dose.
- BRAVELLE® may be given under your skin (subcutaneously) or into your muscle (intramuscularly). Your healthcare provider will tell you where and how to give your BRAVELLE®.
- Your healthcare provider will give you BRAVELLE® intramuscularly.
- BRAVELLE® may be mixed with MENOPUR® in the same syringe when you give it subcutaneously.

**What are possible side effects of BRAVELLE®?**

**BRAVELLE® may cause serious side effects, including:**

- **serious allergic reactions**. Symptoms of allergic reactions include:
    - rash
    - swelling or your face and throat
    - rapid swelling all over your body
    - trouble breathing

  If you have a serious allergic reaction, stop using BRAVELLE® and call your healthcare provider or go to the nearest hospital emergency room right away.

- **ovaries that are too large.** BRAVELLE® may cause your ovaries to be abnormally large. Symptoms of large ovaries include bloating or pain in your lower stomach (pelvic) area. If your ovaries become too large your healthcare provider may tell you that you should not have intercourse (sex) so you do not rupture an ovarian cyst.
- **ovarian hyperstimulation syndrome (OHSS).** Using BRAVELLE® may cause OHSS. OHSS is a serious medical condition that can happen when your ovaries produce too many eggs (overstimulated). OHSS can cause fluid to suddenly build up in the area of your stomach, chest, and heart, and cause blood clots to form. OHSS may also happen after you stop using BRAVELLE®. Stop using BRAVELLE® and call your healthcare provider or go to the nearest hospital emergency room right away if you have any of the following symptoms of OHSS:
    - severe pelvic or stomach pain
    - nausea
    - vomiting
    - sudden weight gain
    - swollen stomach
    - diarrhea
    - trouble breathing
    - decreased or no urine

- **lung problems.** BRAVELLE® may cause serious lung problems that can sometimes lead to death including fluid in the lungs, trouble breathing, and worsening of asthma.
- **blood clots.** BRAVELLE® may increase your chance of having blood clots in your blood vessels. Blood clots can cause:
  - blood vessel problems (thrombophlebitis)
  - stroke
  - loss of your arm or leg
  - blood clot in your lung (pulmonary embolus)
- **twisted (torsion) of your ovaries.** BRAVELLE® may increase the chance of your ovary twisting, if you already have certain conditions such as OHSS, pregnancy and previous abdominal surgery. Twisting of your ovary may lead to blood flow being cut off to your ovary.
- **pregnancy with and birth of multiple babies.** BRAVELLE® may increase your chance of having a pregnancy with more than 1 baby. Having a pregnancy and giving birth to more than 1 baby at a time increases the health risk for you and your babies. Your healthcare provider should talk to you about your chances of multiple births before you start using BRAVELLE®.
- **birth defects in your unborn baby.** Babies born after ART may have an increased chance of birth defects. Your age, certain sperm problems, your genetic background and that of your partner, and a pregnancy with more than 1 baby at a time may increase the chance that your baby may have birth defects.
- **ectopic pregnancy (pregnancy outside your womb).** BRAVELLE® may increase your chance of having a pregnancy that is abnormally outside of your womb. Your chance of having a pregnancy outside of your womb is increased if you also have fallopian tube problems.
- **miscarriage.** Your chance of loss of an early pregnancy may be increased if you had difficulty becoming pregnant.
- **tumors of the ovary.** If you have used medicines like BRAVELLE® more than 1 time to get pregnant, you may have an increased chance of having tumors in your ovaries, including cancer.

The most common side effects of BRAVELLE® include:

- stomach cramps
- stomach fullness and bloating
- headache
- nausea
- pain
- pelvic pain
- hot flashes
- trouble breathing
- pain after egg removal (retrieval)

These are not all the possible side effects of BRAVELLE®. For more information, ask your healthcare provider or pharmacist.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

**How should I store BRAVELLE®?**

- Before mixing, store BRAVELLE® powder in the refrigerator or at room temperature between 37ºF to 77ºF (3ºC to 25ºC).

- Protect BRAVELLE® from light.
- BRAVELLE® should be used right after mixing.
- Throw away any unused BRAVELLE®.

**Keep BRAVELLE® and all medicines out of the reach of children.**

**General information about the safe and effective use of BRAVELLE®.**
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use BRAVELLE® for a condition for which it was not prescribed. Do not give BRAVELLE® to other people, even if they have the same condition you have. It may harm them.

This Patient Information summarizes the most important information about BRAVELLE®. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about BRAVELLE® that is written for health professionals.

For more information go to www.bravelle.com, or call **1-888-FERRING (1-888-337-7464)**.

**What are the ingredients in BRAVELLE®?**

Active ingredient: urofollitropin
Inactive ingredients: lactose monohydrate, polysorbate, sodium phosphate dibasic, heptahydrate and phosphoric acid

**Instructions for Use**

**BRAVELLE® (brä-vel)**

(urofollitropin for injection, purified)
for subcutaneous use

Your healthcare provider should show you how to mix and inject **BRAVELLE® or BRAVELLE® mixed with MENOPUR®** before you do it for the first time. Before using BRAVELLE® or BRAVELLE® mixed with MENOPUR® for the first time, read this **Instructions for Use** carefully. Keep this leaflet in a safe place and read it when you have questions.

**Supplies you will need to give your injection of BRAVELLE® or BRAVELLE® mixed with MENOPUR®. See Figure A.**

- a clean, flat surface to work on, like a table
- vials of BRAVELLE® powder (and MENOPUR® powder if you are going to mix the 2 medicines)
- vials of 0.9% Sodium Chloride, USP used for mixing the medicine
- alcohol pads
- rubbing alcohol
- gauze pads
- a sterile syringe and needle. Your healthcare provider should tell you which syringe and needle to use.
- the Q•Cap® that comes with your medicine
- a sharps disposal container for throwing away your used needles and syringes. See "**Disposing of your used needles and syringes**" at the end of these instructions.

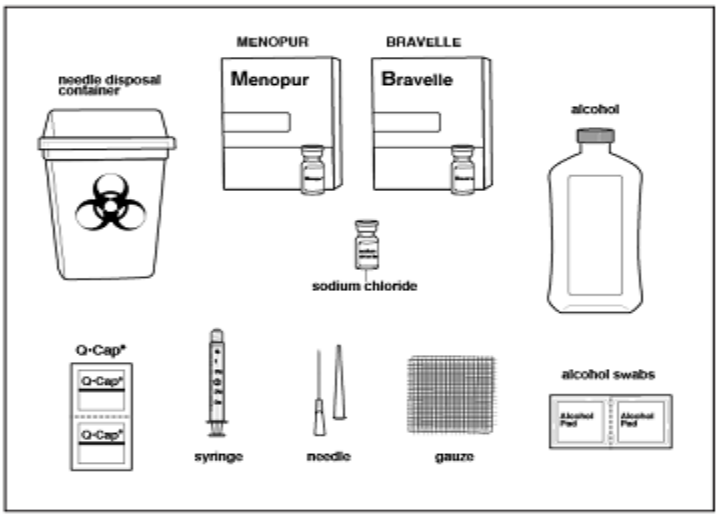


**Figure A**

**Step 1. Preparing your BRAVELLE® or BRAVELLE® mixed with MENOPUR®.**

- Wash your hands well with soap and water. Dry your hands with a clean towel.
- Place all the supplies you need on the clean surface you already prepared.
- Open the Q•Cap® by peeling back the label. **See Figure B.**

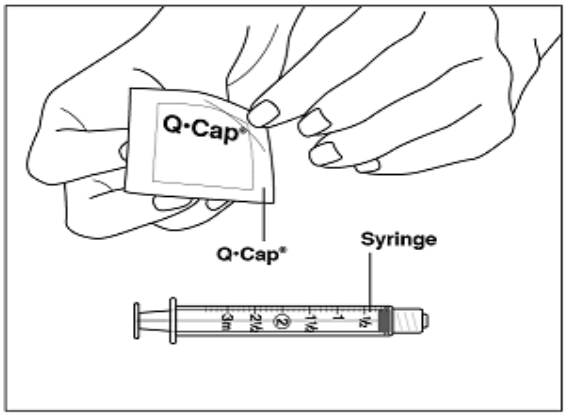


**Figure B**

- Set aside the blister pouch with the Q•Cap®. Do not take the Q•Cap® out of the pouch at this time. Do not touch the ends of the Q•Cap®.

- Remove the plastic caps from the vials of BRAVELLE® (and MENOPUR® if needed) and 0.9% Sodium Chloride, USP. **See Figure C**.

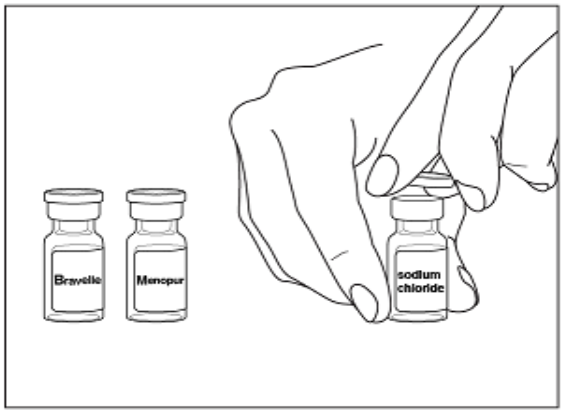


**Figure C**

- Check the vial of BRAVELLE® (and MENOPUR® if needed) to make sure there is powder or a pellet in the vial. Check the 0.9% Sodium Chloride, USP vial to make sure that there are no particles in the liquid and the liquid in the vial is clear. If you do not see powder or see particles or the liquid is discolored, do not use the vial and call your pharmacist or healthcare provider.

- Wipe the tops of the vials with alcohol and allow them to dry. Do not touch the tops of the vials after you have wiped them. **See Figure D.**

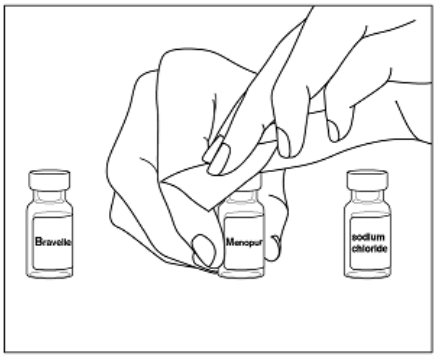


**Figure D**

- Place the vial of 0.9% Sodium Chloride, USP on the table. Remove the Q•Cap® from the blister pouch by grasping the sides with your fingers. **See Figure E.** Carefully twist the syringe onto the connector end (luer) of the Q•Cap® until you feel a slight resistance. Do not touch the spike at the end of the Q•Cap®. **See Figure E.**

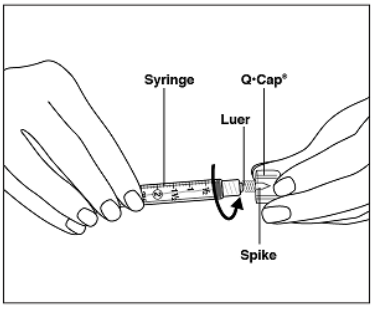


**Figure E**

- Pull down on the syringe plunger until you have withdrawn the amount of 0.9% Sodium Chloride, USP from the vial that your healthcare provider told you to use.
    - The usual amount of 0.9% Sodium Chloride, USP used to mix your BRAVELLE® is 1 mL, but you should use the amount that your healthcare provider tells you to use. **See Figure F.**

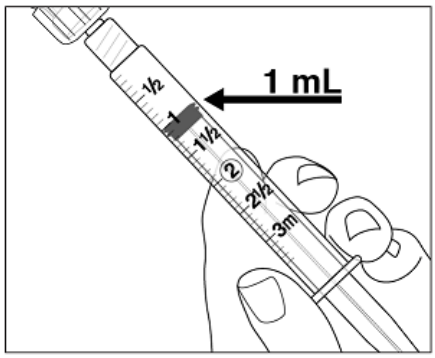


**Figure F**

- Hold the syringe and place the spike end of the Q•Cap® over the top of the 0.9% Sodium Chloride, USP vial. Push the tip of the Q•Cap® into the rubber stopper of the vial until it stops. Be careful not to push down on the syringe plunger during this step. **See Figure G.**

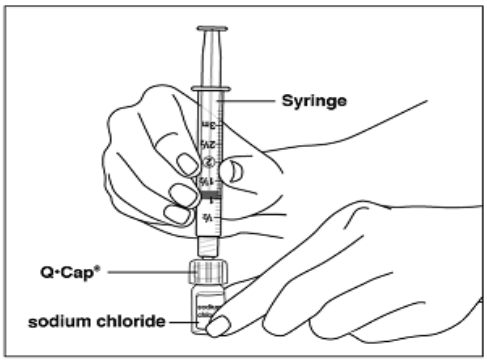


**Figure G**

- Slowly push on the syringe plunger down to move the air from the syringe into the vial. Keeping the syringe and Q•Cap® together, turn the vial upside down and pull down on the syringe plunger to withdraw the right amount of 0.9% Sodium Chloride, USP from the vial. Your healthcare provider should tell you the right amount of 0.9% Sodium Chloride, USP to use. **See Figure H.**

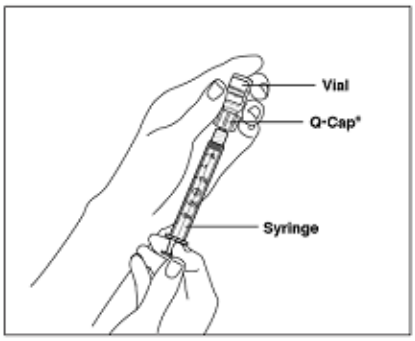


**Figure H**

- Place the 0.9% Sodium Chloride, USP vial on the table. Remove the Q•Cap® and syringe from the vial by pulling up on the syringe barrel. Throw away the 0.9% Sodium Chloride, USP vial in your household trash. **See Figure I.**

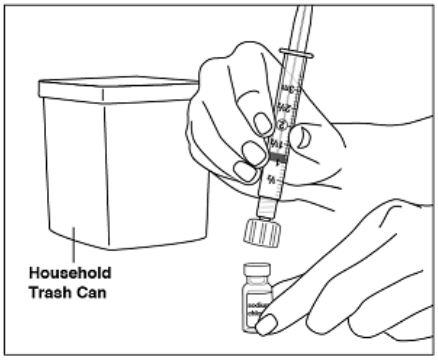


**Figure I**

- Hold the vial of BRAVELLE® powder in 1 hand. Hold the sides of the syringe with your other hand and place the tip of the Q•Cap® over the top of the vial. Push the tip of the Q•Cap® into the rubber stopper of the vial until it stops. Be very careful not to push down on the syringe plunger during this step. **See Figure J.**

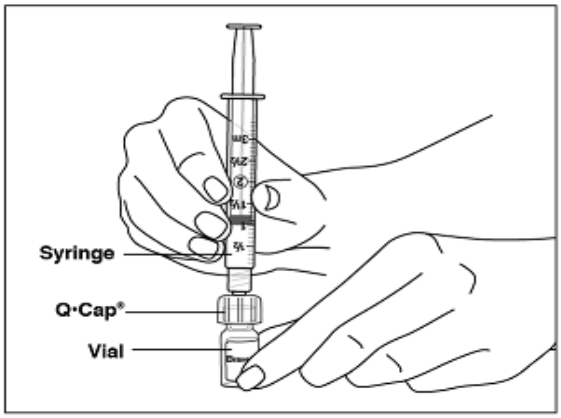


**Figure J**

- Slowly push down on the syringe plunger to push the 0.9% Sodium Chloride, USP into the vial with the BRAVELLE® powder in it. Gently swirl the vial until the BRAVELLE® powder is completely dissolved. **Do not shake** the vial as this will cause bubbles. **See Figure K.**

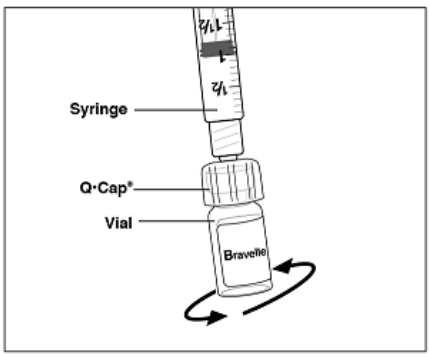


**Figure K**

- As soon as the powdered medicine has completely dissolved, turn the vial upside down and pull down on the plunger to withdraw all of the BRAVELLE® into the syringe. **See Figure L.**

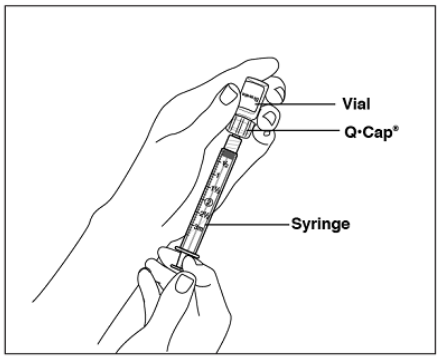


**Figure L**

**If your healthcare provider tells you to use more than 1 vial of BRAVELLE® or tells you to mix your BRAVELLE® with MENOPUR® in the same syringe:**

- Mix your first vial of BRAVELLE® powder or MENOPUR® powder with 0.9% Sodium Chloride, USP. **Do not** inject your dose yet.
- Use the liquid in the syringe you have just mixed to mix the next vial of BRAVELLE® or MENOPUR®. **See Figure J through Figure L.**
- You can use the liquid in the syringe to mix up to 5 more vials of medicine.
- Your healthcare provider will tell you how many vials of BRAVELLE® and MENOPUR® to use.

**Step 2. Removing the Q•Cap® and adding your needle for injection.**

- When you have finished mixing the last vial needed for your injection and have withdrawn all the medicine into the syringe, remove the syringe from the Q•Cap®.

- Twist the syringe counter-clockwise while holding the Q•Cap® steady. Carefully remove the syringe from the Q•Cap®. **See Figure M.** Throw away the Q•Cap® with the attached medicine vial into your household trash. Carefully set the syringe with the medicine down on the table, being careful not to touch the tip of the syringe.

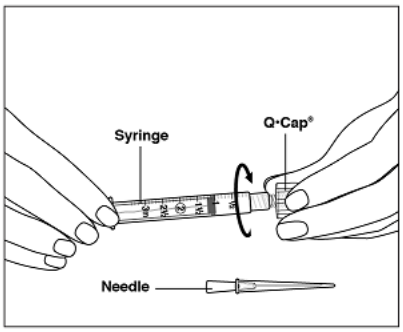


**Figure M**

• You are now ready to attach the needle to the syringe for your injection.
**Your healthcare provider will tell you what needle you should use for your injection.**

• While holding the syringe tip pointing up, place the needle on top of the syringe. Gently push down on the needle and twist the needle onto the syringe in a clockwise direction until it is tight. **See Figure N.**

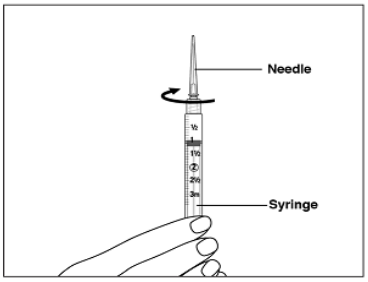


**Figure N**

• Hold the syringe with the needle pointing straight up. Pull down slightly on the plunger and tap the barrel of the syringe so that any air bubbles rise to the top. Slowly press the plunger until all the air is out of the syringe and a small drop of liquid is seen at the tip of the needle. **See Figure O.**

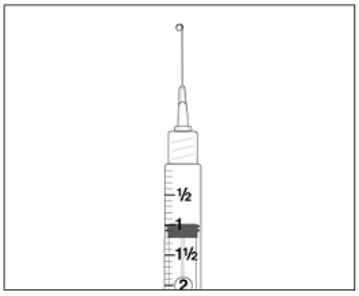

**Figure O**

• Tap the syringe to remove the small drop of liquid at the tip of the needle. **See Figure P.**

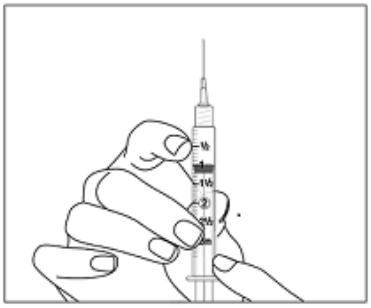

**Figure P**

• Carefully set the syringe with needle down on the table. **Do not** let the needle touch anything to keep it sterile. The medicine is now ready for you to inject. **See Figure Q.**

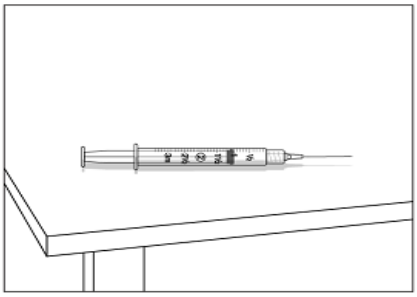

**Figure Q**

**Step 3. Injecting BRAVELLE® or BRAVELLE® mixed with MENOPUR®.**

• Select a site to inject BRAVELLE® or BRAVELLE® mixed with MENOPUR® on your stomach area (abdomen).

- Pick a site on your lower abdomen, 1-2 inches below the navel, alternating between left and right sides.
- Each day, inject in a different site to help reduce soreness and skin problems. For example, on day 1, inject yourself on the right side of your abdomen. The next day, inject yourself on the left side of your abdomen. Changing your injection sites every day will help reduce soreness and skin problems. **See Figure R.**

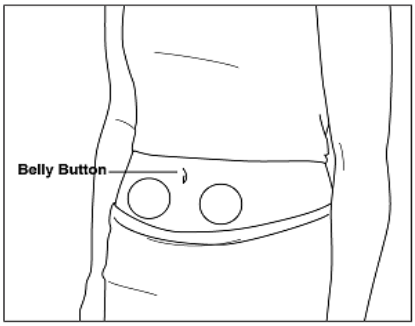


**Figure R**

• Clean your injection site with an alcohol pad. Let the alcohol dry. **See Figure S.**

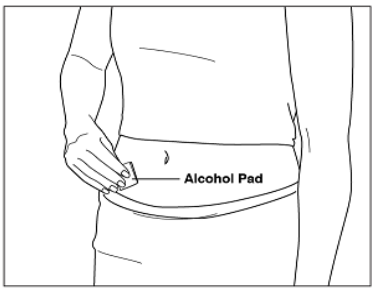


**Figure S**

• Carefully remove the needle cap from the syringe. **See Figure T.**

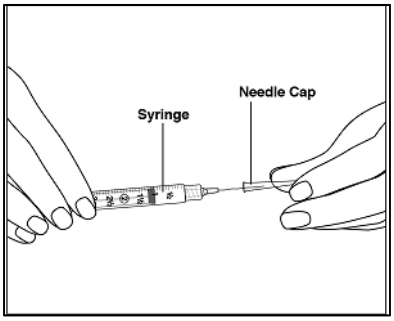


**Figure T**

• Hold the syringe in 1 hand. Use your other hand to gently hold a fold of skin where you will insert your needle. Hold the skin between your thumb and index finger. **See Figure U.**

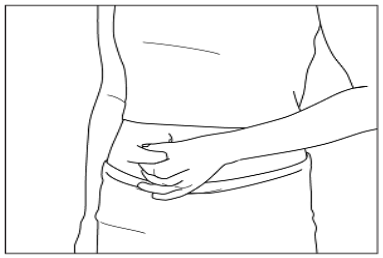

**Figure U**

• Hold your syringe at a right angle to your skin, like a dart. Quickly insert the needle all the way into your skin fold. **See Figure V.**

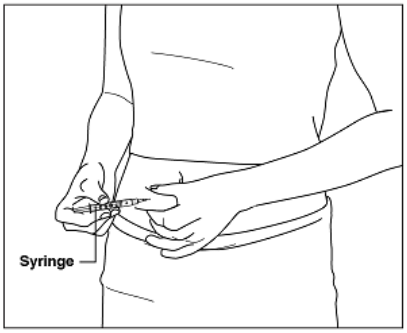


**Figure V**

• Push the plunger of the syringe with a steady motion. Keep pushing until all the fluid is injected into your skin. **See Figure W.**

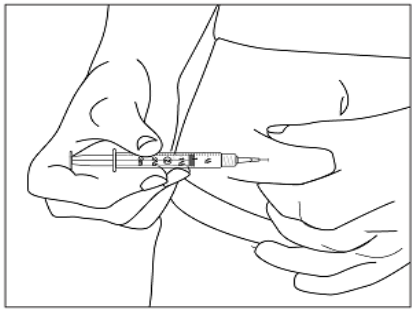

**Figure W**

• Let go of your skin fold and pull the needle straight out of your skin. **See Figure X.**

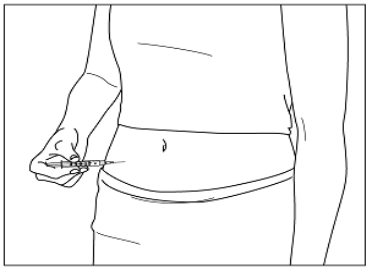

**Figure X**

**Step 4. After your injection.**

• If there is any bleeding at your injection site, place a gauze pad over your injection site. Apply gentle pressure to stop the bleeding. Do not rub the site. **See Figure Y.**

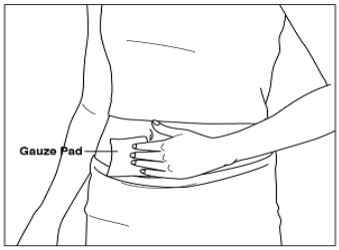


**Figure Y**

• If your injection site becomes sore or red, you may put ice on your injection site for 1 minute and then take it off for 3 minutes. If needed, you may repeat this 3 or 4 times.

**Step 5. Disposing of your used needles and syringes.**

- Put your used needles and syringes in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles and syringes in your household trash.**
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
  - made of a heavy-duty plastic,
  - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
  - upright and stable during use,
  - leak-resistant, and
  - properly labeled to warn of hazardous waste inside the container.

- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal.

  Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

This Patient Information and Instructions for Use has been approved by the U.S. Food and Drug Administration.

**MANUFACTURED FOR:**

FERRING
PHARMACEUTICALS

FERRING PHARMACEUTICALS INC.
PARSIPPANY, NJ 07054

6317-06
Revised 02/2014