

Akorn Announces FDA-approved Generic Cetrorelix Acetate for Injection 0.25 mg

Gurnee, ILL – (PRNewswire) Akorn Operating Company LLC, a specialty pharmaceutical company, announces that it received FDA approval for a generic version of Cetrorelix Acetate for Injection, 0.25 mg (Cetrorelix). This is the first approved AP-Rated bioequivalent version of Merck Serono’s Cetrotide®.¹

“We are pleased to announce the first approved AP-rated generic option for women receiving fertility treatments,” says Akorn President and CEO Douglas Boothe. “As an increasing number of infants are being conceived via the use of ART, Akorn is excited to be able to offer a competitively priced option to support women who undergo this series of treatments. This is a welcome addition to our portfolio of more than 200 specialty and injectable generics.”

Assisted Reproductive Technology (ART) is defined as fertility treatments where eggs or embryos are handled for the purpose of establishing a pregnancy.²

The FDA granted Akorn a Competitive Generic Therapy (CGT) designation for Cetrorelix, a designation intended to incentivize effective development, efficient review, and timely market entry of drugs for which there is inadequate generic competition. As the first approved applicant with the CGT designation, Akorn’s Cetrorelix is eligible for 180 days of CGT market exclusivity, which will begin to run from the commercial launch of Cetrorelix.

According to IQVIA, U.S. sales of Cetrorelix through June of 2022 were approximately \$63 million with full year U.S. sales projection of approximately \$127 million.

About Cetrorelix Acetate for Injection 0.25 mg

Cetrorelix is used to prevent premature ovulation during controlled ovarian stimulation.

Cetrorelix blocks the effects of a natural hormone, called gonadotropin-releasing hormone (GnRH). GnRH controls the secretion of another hormone, called luteinizing hormone (LH), which induces ovulation during the menstrual cycle. During hormone treatment for ovarian stimulation, premature ovulation may lead to eggs that are not suitable for fertilization. Cetrorelix Acetate for Injection blocks such undesirable premature ovulation.

Consult your doctor before taking Cetrorelix if you have had severe allergic reactions.

Do not use Cetrorelix Acetate for Injection if you:

- have kidney disease;
- are allergic to cetrorelix acetate, mannitol or exogenous peptide hormones (medicines similar to cetrorelix acetate for injection); or
- are pregnant, or think that you might be pregnant, or if you are breast-feeding.

About Akorn

Akorn Operating Company LLC, develops, manufactures and markets specialty pharmaceuticals. Since

1971, as an industry leader in generic products in alternate dosage forms such as ophthalmics, injectables, oral liquids, otics, topicals, inhalants and nasal sprays, we focus each day on our mission to improve lives, through the quality, availability and affordability of our products. Additional information is available on Akorn's website at www.akorn.com.

¹The use of the name "Merck" and "Merck Serono" in this press release refers to Merck KGaA of Darmstadt, Germany. In North America, Merck KGaA operates under the umbrella brand EMD.

² <https://www.cdc.gov/art/state-specific-surveillance/>