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Generic Name:

Follitropin alfa injection

Trade Name:

Gonal-f RFF Redi-ject, Gonal-f Multi-Dose

Company: EMD Serono

Notes:

FDA is alerting health professionals, patients, and the drug supply chain of <u>stolen injectable fertility</u> <u>medications</u> Gonal-f RFF Redi-ject, Gonal-f Multi-Dose (follitropin alfa injection). Patients who have product with these <u>lot numbers</u> should not use them.

All product with these lot numbers were in this stolen shipment. The lot numbers are located on the flap of each box, below the tamper-proof seal and next to the 2D barcode.

The products were stolen in Italy on May 17, 2018, and were intended to be shipped to the United States. EMD Serono of Rockland, MA, reported the theft of more than 16,000 packages of follitropin alfa injection to FDA on May 18, 2018.

Drug supply chain stakeholders that receive or possess these lot numbers must <u>notify</u> FDA via <u>Form FDA 3911</u>. Anyone who has received suspicious or unsolicited offers to purchase follitropin alfa injection products since May 17, 2018, should contact <u>FDA Office of Criminal Investigations</u> at 800-551-3989.

Drug supply chain stakeholders should continue to remain vigilant when buying or selling these products and check the lot number to prevent stolen product from entering the drug supply chain.

Patients, health professionals, and drug supply chain stakeholders should check the product and label for signs of tampering before using.

FDA also reminds health professionals, patients, and drug supply chain stakeholders to purchase products only from licensed wholesale distributors and pharmacies. See FDA?s <u>Know Your Source</u> and <u>BeSafeRx</u> programs for more information.

Medication Monitor Categories:

Alerts and Recalls

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