

FDA approves new GONAL-f Prefilled Pen by Merck

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New pen is easy-to-learn and easy-to-use, supporting the one in six couples affected by infertility in the U.S.



Merck, a leading science and technology company, has received approval for a new version of GONAL \mathcal{f} (follitropin alfa injection) prefilled pen from the U.S. Food and Drug Administration (FDA). Known as GONAL \mathcal{f} RFF Redi-ject prefilled pen in the U.S. and originally approved by the FDA in 2013, the new version of the pen is easy-to-learn and easy-to-use.

Aspiring to be an integrated fertility treatment partner, our strategy focuses on developing user-friendly treatment options for patients," said Luciano Rossetti, Head of Global Research and Development, at the biopharma business of Merck. "We understand that the best drivers for innovation come from insights from the people using our products. Their advice was a significant factor in the development of the new version of the GONAL \mathcal{f} prefilled pen."

To date, an estimated 2.5 million babies have been brought to the world with the help of Merck fertility products and services. GONAL \mathcal{f} is the only gonadotropin that comes in prefilled, ready-to-use pen in the U.S. The new GONAL \mathcal{f} pen, like its predecessor, enables a fine-tuning of treatment allowing for minimum increments of 12.5 IU to titrate a wide range of doses and precisely target the dosing to patients' needs. In addition, its new design features include an amendment to the dose display window for readability.

Patients suffering from infertility are a key focus for Merck as the company continuously seeks to expand its fertility offering. The latest version of the GONAL \mathcal{f} prefilled pen is the most recent addition to Merck's growing portfolio to support women and couples faced with infertility in the U.S., where one in six couples is affected by infertility.