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EPAR summary for the public

Bemfola

follitropin alfa

This is a summary of the European public assessment report (EPAR) for Bemfola. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Bemfola.

For practical information about using Bemfola, patients should read the package leaflet or contact their doctor or pharmacist.

What is Bemfola and what is it used for?

Bemfola is a medicine that contains the active substance follitropin alfa. It is used to treat the following groups:

- women who do not produce eggs and who do not respond to treatment with clomiphene citrate (another medicine that stimulates the ovaries to produce eggs);
- women who are undergoing assisted reproductive techniques (fertility treatment) such as *in vitro* fertilisation. Bemfola is given to stimulate the ovaries to produce more than one egg at a time;
- women with severe deficiency (very low levels) of luteinising hormone (LH) and follicle stimulating hormone (FSH). Bemfola is given together with a medicine containing LH to stimulate the eggs to mature in the ovaries;
- men who have hypogonadotrophic hypogonadism (a rare hormone deficiency disease). Bemfola is used together with human chorionic gonadotrophin (hCG) therapy to stimulate sperm production.

Bemfola is a 'biosimilar medicine'. This means that Bemfola is similar to a biological medicine (also known as the 'reference medicine') that is already authorised in the European Union (EU). The reference medicine for Bemfola is GONAL-f. For more information on biosimilar medicines, see the question-and-answer document here.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

How is Bemfola used?

Bemfola is available as a solution for injection in a prefilled pen. The medicine can only be obtained with a prescription and treatment should be started under the supervision of a doctor who has experience in the treatment of fertility problems

Bemfola is given by injection under the skin once a day. The dose of Bemfola and how often it is given depend on why it is being used and on the patient's response to treatment. After the first injection, the patient or their partner may give the injections themselves, if they are well motivated, have been trained and have access to expert advice.

For further information, see the package leaflet.

How does Bemfola work?

The active substance in Bemfola, follitropin alfa, is a copy of the natural hormone FSH. In the body, FSH controls reproductive function: in women, it stimulates the production of eggs in the ovaries; in men, it stimulates the production of sperm in the testicles.

Previously, the FSH used in medicines was extracted from urine. The follitropin alfa in Bemfola, as well as in the reference product GONAL-f, is produced by a method known as 'recombinant DNA technology': it is made by cells into which a gene (DNA) has been introduced, which makes them able to produce human FSH.

What benefits of Bemfola have been shown in studies?

Bemfola was compared with GONAL-f in one main study involving 372 women who were undergoing assisted reproductive techniques. The main measure of effectiveness was the number of eggs collected.

Bemfola has been shown to be comparable to the reference medicine, GONAL-f. The study showed that Bemfola was as effective as GONAL-f at stimulating the ovaries during assisted reproductive techniques, as an average of 11 eggs were retrieved with both medicines.

What are the risks associated with Bemfola?

The most common side effects with Bemfola (which may affect more than 1 in 10 people) are reactions at the injection site (pain, redness, bruising, swelling or irritation). In women, ovarian cysts (sacs of fluid within the ovaries) and headache are also seen in more than 1 patient in 10. For the full list of all side effects reported with Bemfola, see the package leaflet.

Bemfola must not be used in people who are hypersensitive (allergic) to follitropin alfa, FSH, or any of the other ingredients. It must not be used in patients with tumours of the pituitary gland or hypothalamus, or cancer of the breast, womb or ovary. It must not be used when it would not be possible for the patient to have an effective response, such as in patients whose ovaries or testicles do not work or in women who should not get pregnant for medical reasons. In women, Bemfola must not be used when there is enlargement of an ovary or a cyst that is caused by something other than polycystic ovarian disease, or when there is unexplained bleeding from the vagina. For the full list of restrictions, see the package leaflet.

In some women, the ovaries can over-respond to stimulation. This is called 'ovarian hyperstimulation syndrome'. Doctors and patients must be aware of this possibility. For more information, please see the package leaflet.

Why is Bemfola approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that, in accordance with EU requirements for biosimilar medicines, Bemfola has been shown to have a comparable quality, safety and effectiveness to GONAL-f. Therefore, the CHMP's view was that, as for GONAL-f, the benefits of Bemfola outweigh the identified risks. The Committee recommended that Bemfola be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Bemfola?

A risk management plan has been developed to ensure that Bemfola is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Bemfola, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Bemfola

The European Commission granted a marketing authorisation valid throughout the European Union for Bemfola on 27 March 2014.

The full EPAR and risk management plan summary for Bemfola can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Bemfola, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2014.