EMA/356673/2023
EMEA/H/C/006048

Degarelix Accord (*degarelix*)

An overview of Degarelix Accord and why it is authorised in the EU

What is Degarelix Accord and what is it used for?

Degarelix Accord is a medicine used to treat cancer of the prostate (a gland of the male reproductive system) in adult men when the cancer is hormone-dependent, which means that it responds to treatments that reduce the levels of the hormone testosterone. It is used:

- to treat advanced hormone-dependent prostate cancer. 'Advanced' means that the cancer has spread beyond the pelvis to nearby tissues such as lymph nodes and bone;
- before or together with radiotherapy to treat high-risk localised or locally advanced hormone-dependent prostate cancer. 'High-risk localised' means that the cancer is likely to spread beyond the prostate gland to nearby tissues and become 'locally advanced'.

Degarelix Accord contains the active substance degarelix and is a 'generic medicine'. This means that Degarelix Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Degarelix Accord is Firmagon. For more information on generic medicines, see the question-and-answer document here.

How is Degarelix Accord used?

Degarelix Accord is injected under the skin of the abdomen (belly). Treatment starts with two injections given one after the other in the first month, followed by a single injection every month. Doctors should monitor the effectiveness of Degarelix Accord treatment by looking at blood levels of testosterone and prostate-specific antigen (PSA). PSA is a protein that is produced by the prostate gland and is often found at high levels in men with prostate cancer.

The medicine can only be obtained with a prescription. For more information about using Degarelix Accord, see the package leaflet or contact your doctor or pharmacist.

How does Degarelix Accord work?

Testosterone can make prostate cancer cells grow. The active substance in Degarelix Accord, degarelix, reduces the amount of testosterone in the body by blocking the effects of a natural hormone called gonadotrophin-releasing hormone (GnRH). GnRH is the first step in a system responsible for testosterone production. By blocking GnRH, Degarelix Accord slows down the growth of the cancer

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

cells. When injected, Degarelix Accord forms a gel under the skin that releases the active substance slowly over a few weeks.

How has Degarelix Accord been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Firmagon, and do not need to be repeated for Degarelix Accord.

As for every medicine, the company provided studies on the quality of Degarelix Accord. There was no need for 'bioequivalence' studies to investigate whether Degarelix Accord is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because the composition of Degarelix Accord is very similar to that of the reference medicine and when given by injection under the skin, the active substance in both products is expected to be absorbed in the same way.

What are the benefits and risks of Degarelix Accord?

Because Degarelix Accord is a generic medicine, its benefits and risks are taken as being the same as those of the reference medicine.

Why is Degarelix Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Degarelix Accord has been shown to be comparable to Firmagon. Therefore, the Agency's view was that, as for Firmagon, the benefits of Degarelix Accord outweigh the identified risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Degarelix Accord have been included in the summary of product characteristics and the package leaflet.

Any additional measures in place for Firmagon also apply to Degarelix Accord where appropriate.

As for all medicines, data on the use of Degarelix Accord are continuously monitored. Suspected side effects reported with Degarelix Accord are carefully evaluated and any necessary action taken to protect patients.

Other information about Degarelix Accord

Degarelix Accord received a marketing authorisation valid throughout the EU on 29 September 2023.

Further information on Degarelix Accord can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/degarelix-accord.

Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 09-2023.