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Firmagon (*degarelix*)

An overview of Firmagon and why it is authorised in the EU

What is Firmagon and what is it used for?

Firmagon 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'.

Firmagon contains the active substance degarelix.

How is Firmagon used?

Firmagon is injected under the skin of the abdomen. Treatment starts with two 120-mg injections, followed by single 80-mg injections every month. Doctors should monitor the effectiveness of Firmagon 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 Firmagon, see the package leaflet or contact your doctor or pharmacist.

How does Firmagon work?

Testosterone can make prostate cancer cells grow. The active substance in Firmagon, 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, Firmagon slows down the growth of the cancer cells. When

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injected, Firmagon forms a gel under the skin that releases the active substance slowly over a few weeks.

What benefits of Firmagon have been shown in studies?

A main study involving 610 men with prostate cancer at all stages of the disease showed that Firmagon is effective at reducing the amount of testosterone to levels seen in men whose testicles have been surgically removed.

In this study, Firmagon was as effective as leuprorelin (another medicine for prostate cancer). During the first year, 97% of the patients receiving Firmagon at the approved dose of 80 mg once a month dose had testosterone levels below the required level. This was compared with 96% of patients receiving leuprorelin.

A second study involving 244 men with intermediate- to high-risk prostate cancer found that Firmagon was as effective at reducing the prostate volume before radiotherapy as a combination of two other prostate cancer medicines, goserelin and bicalutamide. After 12 weeks of treatment, prostate volume decreased by 36.0% in patients treated with Firmagon and 35.3% in those receiving goserelin and bicalutamide.

What are the risks associated with Firmagon?

The most common side effects with Firmagon (which may affect more than 1 in 10 people) are hot flushes and reactions at the injection site such as pain and redness.

For the full list of side effects and restrictions of Firmagon, see the package leaflet.

Why is Firmagon authorised in the EU?

The European Medicines Agency decided that Firmagon's benefits are greater than its risks and it can be authorised for use in the EU.

Firmagon was as effective as leuprorelin in the treatment of advanced hormone-dependent prostate cancer. In addition, Firmagon was also effective for high-risk localised or locally advanced prostate cancer before radiotherapy. Based on its mechanism of action, the Agency considered that Firmagon can also be expected to be effective for high-risk localised or locally advanced prostate cancer in combination with radiotherapy. This will be further confirmed in an ongoing study.The agency also noted that treatment with Firmagon does not trigger the temporary sharp rise in testosterone levels seen with 'GnRH agonists' (other medicines for prostate cancer that stimulate the production of GnRH). This means that patients do not need to take other medicines to block testosterone at the start of treatment.

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

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

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

Other information about Firmagon

Firmagon received a marketing authorisation valid throughout the EU on 17 February 2009.

Further information on Firmagon can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/firmagon

This overview was last updated in 10-2021.