EMA/567567/2022
EMEA/H/C/004837

Camcevi (*leuprorelin*)

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

What is Camcevi and what is it used for?

Camcevi is a medicine used in adult men for the treatment of advanced prostate cancer that is 'hormone-dependent', meaning that it responds to treatments that lower the level of the hormone testosterone. Camcevi is also used in combination with radiotherapy to treat locally advanced hormone-dependent prostate cancer and high-risk localised prostate cancer (this means that the cancer is likely to spread beyond the prostate gland to nearby tissues and become 'locally advanced') .

Camcevi is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance but has a different formulation. The reference medicine for Camcevi is Eligard. Camcevi is available as a ready-to-use medicine in contrast with Eligard, which requires pre-mixing before it can be given to the patient.

The active substance in Camcevi is leuprorelin.

How is Camcevi used?

Camcevi is available as prolonged-release suspension for injection in a pre-filled syringe. Prolonged-release means that the active substance is released slowly over a six-month period after being injected. Injections are given under the skin.

Camcevi can only be obtained with a prescription. Treatment should be given by a healthcare professional experienced in using the medicine and under the supervision of a doctor experienced in monitoring the treatment of prostate cancer.

For more information about using Camcevi, see the package leaflet or contact your doctor or pharmacist.

How does Camcevi work?

Testosterone can make prostate cancer cells grow. When present continuously, the active substance in Camcevi, leuprorelin, 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 and thus reducing the level of testosterone,

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Camcevi slows down the growth of the cancer cells. When injected, Camcevi forms a gel under the skin that releases the active substance slowly over six months.

What benefits of Camcevi have been shown in studies?

The company provided data from the published literature on the benefits and risks of leuprorelin in the approved use.

As for every medicine, the company provided studies on the quality of Camcevi. They also presented results from a study which showed that treatment with Camcevi lowered the amount of testosterone to levels comparable to those previously reported for the reference medicine. This study included 137 men with hormone-dependent prostate cancer who were given two doses of Camcevi 24 weeks apart. Four weeks after the first injection, 98.5% (135 out of 137) of patients experienced a decrease in testosterone to levels similar to those seen in men after chemical or surgical castration. Testosterone levels remained below castration levels during the 48-week treatment period in 97% (133 out of 137) patients.

What are the risks associated with Camcevi?

The most common side effect with Camcevi (which may affect more than 1 in 2 people) is the occurrence of mild or moderate hot flushes. Other side effects include nausea, malaise (feeling generally unwell), tiredness and irritation at the injection site.

For the full list of side effects of Camcevi, see the package leaflet.

Camcevi must not be used in patients whose testicles have been surgically removed, as sole treatment in patients with spinal cord compression or those whose cancer has metastasised (spread) to the spine. Camcevi must also not be used in patients allergic to the active substance, to any other ingredients or to other GnRH agonists (substances that attach to a GnRH receptor (target) and trigger an effect).

Why is Camcevi authorised in the EU?

The European Medicines Agency concluded that in accordance with EU requirements, Camcevi has been shown to be comparable to Eligard. In addition, Camcevi's ready-to-use formulation means it is easier to use. Therefore, the Agency decided that Camcevi's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Camcevi

Camcevi received a marketing authorisation valid throughout the EU on 24 May 2022.

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

This overview was last updated in 05-2022.