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Jemperli (*dostarlimab*)

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

What is Jemperli and what is it used for?

Jemperli is a cancer medicine for treating certain types of endometrial cancer (cancer of the womb) that are advanced or have come back. It is used:

- together with carboplatin and paclitaxel (other cancer medicines, also called chemotherapy) in adults whose cancer is suitable for systemic therapy (treatment that affects the whole body);
- on its own in adults whose cancer has got worse despite treatment involving a platinum-based cancer medicine.

Jemperli is for endometrial cancer where the cancer cells have genetic abnormalities (called mismatch repair deficiency and high microsatellite instability) which prevent the cells from correcting mistakes that occur during cell division.

Jemperli contains the active substance dostarlimab.

How is Jemperli used?

Treatment with Jemperli must be started and supervised by a doctor experienced in treating cancer. The medicine can only be obtained with a prescription.

Jemperli is given by infusion (drip) into a vein over 30 minutes. When used alone, it is given once every 3 weeks for the first 4 doses; when used together with carboplatin and paclitaxel, it is given once every 3 weeks for the first 6 doses. It is then given on its own once every 6 weeks.

The doctor will decide how long treatment with Jemperli will last. They may interrupt Jemperli treatment or stop it altogether if certain side effects occur.

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

How does Jemperli work?

The active substance in Jemperli, dostarlimab, is a monoclonal antibody, a protein that has been designed to block a receptor (target) called PD-1 on certain cells of the immune system (the body's natural defences). Some cancers can make proteins (PD-L1 and PD-L2) that combine with PD-1 to

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switch off the activity of the immune cells, preventing them from attacking the cancer. By blocking PD-1, dostarlimab stops the cancer switching off these immune cells, thereby increasing the immune system's ability to kill the cancer cells.

What benefits of Jemperli have been shown in studies?

Jemperli was found effective in 2 studies involving women with endometrial cancer that was advanced or had come back and whose cancer involved mismatch repair deficiency or high microsatellite instability.

The first study involved 108 women whose cancer had got worse despite treatment that included a platinum-containing medicine. At follow up after at least 24 weeks, the cancer had shrunk or could no longer be detected in 43.5% of women receiving Jemperli. Further data from the study confirmed the benefits of Jemperli after an average follow up of around 28 months. In this study, treatment with Jemperli was not compared with another cancer medicine or placebo (a dummy treatment).

Another study involved 118 women whose cancer was advanced or had come back. They received either Jemperli or placebo, given together with carboplatin and paclitaxel chemotherapy for 6 cycles and then on their own. After an average follow up of 25 months, the results showed that women who received placebo plus chemotherapy lived for an average of 8 months without their disease getting worse. For women who received Jemperli plus chemotherapy it was not possible to calculate this duration as not enough of these women had experienced worsening of their disease.

What are the risks associated with Jemperli?

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

The most common side effects with Jemperli used alone (which may affect more than 1 in 10 people) include anaemia (low count of red blood cells), diarrhoea, nausea (feeling sick), vomiting, joint pain, itching, rash, fever, increased levels of liver enzymes (aspartate aminotransferase) and hypothyroidism (low levels of thyroid hormones).

The most common side effects with Jemperli used in combination with carboplatin and paclitaxel (which may affect more than 1 in 10 people) include rash, hypothyroidism, increased levels of liver enzymes (alanine aminotransferase and aspartate aminotransferase) in the blood, fever and dry skin.

Most of the serious side effects with Jemperli used alone or in combination with carboplatin and paclitaxel are related to the medicine's effects on the immune system, such as inflammation in various body organs and tissues, rash and reactions to the infusion.

Why is Jemperli authorised in the EU?

Jemperli has been shown to be effective in the treatment of endometrial cancer that is advanced or has come back. When used in combination with chemotherapy to treat endometrial cancer that is suitable for systemic therapy, Jemperli is effective at increasing the time women live before their disease gets worse. When used on its own, Jemperli has beneficial effects in the treatment of women with endometrial cancer that has returned after treatment, which is difficult to treat. The side effects seen with Jemperli are mainly related to its effects on the immune system and are considered acceptable. The Agency therefore decided that Jemperli's benefits are greater than its risks and it can be authorised for use in the EU.

Jemperli was originally given 'conditional authorisation' because there was more evidence to come about the medicine. As the company has supplied this additional information, the authorisation has been switched from conditional to standard authorisation.

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

The company that markets Jemperli will provide the final results from the study on the effectiveness and safety of Jemperli in combination with carboplatin and paclitaxel in women with endometrial cancer that is advanced or has returned and is suitable for systemic therapy.

The company will also provide a patient card about signs and symptoms of side effects of the immune system of the medicine and the need to get immediate medical help if these side effects occur.

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

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

Other information about Jemperli

Jemperli received a conditional marketing authorisation valid throughout the EU on 21 April 2021. This was switched to a standard marketing authorisation on 07 December 2023.

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

This overview was last updated in 12-2023.