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Jemperli® (active substance: dostarlimab)

Temporary authorisation in Switzerland: 17 February 2022

Medicinal product (concentrate) for the second-line treatment of adults with recurrent or advanced endometrial cancer

About the medicinal product

Jemperli is a cancer treatment containing the active substance dostarlimab.

Jemperli is used to treat adults with recurrent or advanced endometrial cancer (cancer of the lining of the uterus) with defective DNA mismatch repair (dMMR)[1]/ high microsatellite instability (MSI-H)[2].

Jemperli is prescribed for patients whose endometrial cancer has already been treated with other medicines that were not sufficiently effective (second-line treatment).

Mode of action

The active substance dostarlimab is a monoclonal antibody (immunologically active protein) that binds to a specific protein known as PD-1 (programmed cell death receptor-1) and thereby prevents it from binding to the PD-ligand (programmed cell death-ligand). As a result, the immune response is inhibited, and the growth of the cancer can be delayed or stopped.

Use

Jemperli is a prescription-only medicine supplied as a concentrate for solution for infusion that is injected into the veins.

The recommended dosage is 500 mg dostarlimab as a 30-minute infusion every 3 weeks for 4 cycles, followed by 1,000 mg every 6 weeks for all cycles thereafter.

Efficacy

[1] DNA mismatch repair: Mismatch repair (MMR) is a natural mechanism of the body for identifying and correcting (DNA repair proteins) mismatches in the synthesis of DNA (carrier of genetic information in the cells).

[2] Microsatellite instability: A defective DNA mismatch repair results in the accumulation of mutations that can be identified, by comparison with healthy tissue, as a microsatellite instability (MSI).

In the GARNET study with 568 patients with recurrent or advanced endometrial cancer with a defective DNA mismatch repair/high microsatellite instability and who had already been treated with other drugs that failed to curb the progression of the disease, Jemperli showed clinically relevant efficacy.

The proportion of patients with an objectively measured tumour reduction was 44.8%. The duration of the response could not be conclusively established at the time when the clinical study was assessed.

Precautions, undesirable effects & risks

Jemperli must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effects are a low red blood cell count (anaemia), reduced thyroid gland activity, loss of appetite, nausea, diarrhoea, vomiting, increased liver enzyme levels (elevated transaminases), itching, skin rash, tiredness and fever.

All precautions, risks and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

The frequency of endometrial cancers has increased in recent decades. It is often diagnosed at an early stage when it is still curable. If the endometrial cancer recurs or is locally advanced, it continues to be a fatal illness. The standard treatment of choice is a platinum-based treatment regimen. However, no standard second-line treatment exists, and the response rates to various chemotherapy drugs are low and short-lived. Consequently, there is a medical need to improve the treatment of patients with recurrent endometrial cancer.

The GARNET showed clinically significant results, with an objective response rate of 44.8%.

Based on all the available data, the benefits of Jemperli outweigh the risks. The medicinal product Jemperli has been authorised temporarily in Switzerland (in accordance with Art. 9a TPA) since not all clinical trials had been concluded at the time of authorisation. The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic. Once these authorisation conditions have been met, the temporary authorisation can be converted into an ordinary authorisation in the event of a positive benefit-risk assessment of the results.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Jemperli®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.