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Jemperli® (active substance: dostarlimab)

Indication extension in Switzerland: 22 December 2023

Medicinal product for the 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 was originally temporarily authorised on 17 February 2022 as monotherapy for the treatment of adult patients whose endometrial cancer has already been treated with other medicines that were not sufficiently effective (second-line treatment).

The indication extension means that the medicinal product Jemperli can now also be used as first-line treatment in combination with chemotherapy based on carboplatin and paclitaxel for the treatment of adult patients with recurrent or advanced endometrial cancer with dMMR / MSI-H and who are at high risk of disease recurrence.

The indication extension for Jemperli was authorised in connection with "Project Orbis". Project Orbis is a programme for promising cancer treatments coordinated by the FDA, the US regulatory authority. It provides a framework for the concurrent submission and review of cancer medicines by several international partner authorities in various countries. The ultimate aim is to give patients faster access to innovative cancer treatments. Currently, the authorisation authorities in Australia (TGA), Brazil (ANVISA), Israel (MOH), Canada (HC), Singapore (HSA), Switzerland (Swissmedic), and the United Kingdom (MHRA) are represented in Project Orbis.

[1] DNA mismatch repair: Defective mismatch repair (dMMR) 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).

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 inhibited by the tumour is reduced or eliminated, enabling the body's own immune system to better fight the tumour and delay or stop its growth.

Use

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

Use of Jemperli in combination with chemotherapy (indication extension)

The recommended dosage of Jemperli as combination therapy with carboplatin and paclitaxel is 500 mg of dostarlimab every 3 weeks for 6 doses, followed by 1,000 mg every 6 weeks for all subsequent cycles.

Efficacy

The efficacy for the requested indication extension for Jemperli, with the active substance dostarlimab, in combination with carboplatin-paclitaxel was investigated in the RUBY study with a total of 118 patients with primary advanced or recurrent endometrial cancer with defective DNA mismatch repair / high microsatellite instability. The patients who were eligible for the RUBY study had a high risk of disease recurrence.

The RUBY study showed that, in patients who received the combination therapy of Jemperli, with the active substance dostarlimab, and carboplatin-paclitaxel, the probability of a recurrence of the endometrial cancer was reduced and the time to disease recurrence was significantly longer compared to patients who received a treatment with a dummy drug and carboplatin-paclitaxel. An additional predefined analysis also showed that the probability of dying from the illness was reduced.

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.

If the medicinal product Jemperli is administered in combination with other medicinal products (carboplatin-paclitaxel), the Information for healthcare professionals for the respective preparations in the combination therapy should be considered before the start of treatment.

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 if metastases form, it continues to be a fatal illness.

The RUBY study showed that patients with recurrent or advanced endometrial cancer with dMMR / MSI-H and who are at high risk of disease recurrence profit from the treatment with the medicinal product Jemperli in combination with carboplatin-paclitaxel.

Based on all the available data, the benefits of Jemperli outweigh the risks. Swissmedic has therefore approved the indication extension for Jemperli as combination therapy with carboplatin-paclitaxel for the first-line treatment of patients with recurrent or advanced endometrial cancer with dMMR / MSI-H and who are at high risk of disease recurrence.

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.

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