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Besremi® (active substance: ropeginterferon alfa-2b)

First authorisation in Switzerland: 01.07.2020

Medicinal product (solution for injection in pre-filled pen) for the treatment of polycythaemia vera without symptoms of an enlarged spleen

About the medicine

The medicinal product Besremi, containing the active substance ropeginterferon alfa-2b, is a solution for injection under the skin and comes in pre-filled pens.

Besremi is used alone and has been authorised for the treatment of adult patients who have been diagnosed with polycythaemia vera without symptoms of an enlarged spleen.

This rare condition is a chronic blood disorder in which the bone marrow produces too many red blood cells.

Mode of action

The active ingredient in Besremi, ropeginterferon alfa-2b, slows the production of red blood cells in the patient's bone marrow. Ropeginterferon alfa-2b is modified version of interferon, a protein produced by the body that binds with cell receptors and causes certain reactions that slow down the activity of those cells in the bone marrow that produce red blood cells.

Use

Besremi is available by prescription only. Treatment should be given under the supervision of a physician experienced in the management of polycythaemia vera.

Injections can be administered by medical staff or the patient or their caregiver if they have been trained in the use of the pre-filled pens.
Injections are given every 2 weeks under the skin. The dose begins at 100 micrograms and should be increased by 50 micrograms every two weeks until the patient's blood count normalises. The maximum single dose is 500 micrograms every two weeks.

The dose at which a patient's blood count normalises should be continued every 2 weeks for 1.5 years. After that, the dose may be adjusted or spread out to every 4 weeks. Doses can also be adjusted if the patient experiences any adverse effects.

Efficacy

The efficacy of Besremi, with the active substance ropeginterferon alfa-2b, was investigated in a study involving 257 adult patients who had been diagnosed with polycythaemia vera. About half of the patients, 127, received ropeginterferon alfa-2b in an injection under the skin. The other half, 130 patients, received the standard treatment currently in use called hydroxyurea, a pill taken by mouth.

In this study, 43 % of the patients treated with ropeginterferon alfa-2b had normal blood cell counts after 12 months compared with 46 % of patients treated with hydroxyurea.

The response took longer, 28 weeks, in the group given Besremi, compared with the hydroxyurea group, which took 8 weeks to see the red blood cell counts return to normal. However, patients who received Besremi were continuing to improve even as the study ended at 12 months, while those who received hydroxyurea saw no further improvement after 6 months.

Precautions, undesirable effects & risks

Besremi may not be used if the patient has a hypersensitivity to the active ingredient ropeginterferon alfa-2b or any other substance in the injection.

Some patients should not use Besremi, including those with uncontrolled thyroid disease, severe depression, severe heart problems, such as congestive heart failure, and autoimmune diseases, pregnancy.
Side effects were reported in 89.8 % of patients who received Besremi.

The most common side effects were a decline in the disease-fighting white blood cells, seen in 19 % of patients, and fatigue, which was seen in 12 % of patients. Other side effects included flu-like symptoms, fatigue, and muscle pain.

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

Why the medicine has been authorised

Polycythaemia vera is a rare disease in which the patient's bone marrow produces too many red blood cells. This can cause the blood to thicken, reducing blood flow to organs. The patient's spleen may enlarge as it tries to remove excess cells.

Left untreated, half of patients with polycythaemia vera will die within 18 months.

Patients who receive the standard treatment currently in use, hydroxyurea, have a risk of developing cancer, particularly myelofibrosis, a type of bone marrow cancer (up to 50 % of patients after 20 years) and acute myeloid leukaemia (up to 20 %). It is unclear if these cancers are a result of the treatment or the disease.

Besremi takes longer to normalise the patient's red blood cell count, although other short-term treatments can be used in addition during that period, such as one to remove excess blood by bleeding. Besremi could be beneficial for younger patients since it avoids the carcinogenic effects seen in patients treated with hydroxyurea.

Taking all the precautions into account, and based on the available data, the benefits of Besremi outweigh the risks. Swissmedic has therefore authorised the medicine Besremi, with the active ingredient ropeginterferon alfa-2b, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals:
Information for healthcare professionals Besremi®

Healthcare professionals (doctors, pharmacists and others) may answer any further questions.

This information is correct as at the date above. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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