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SCIENCE MEDICINES HEALTH

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Besremi (*ropeginterferon alfa-2b*)

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

What is Besremi and what is it used for?

Besremi is a medicine used to treat polycythaemia vera in adults who do not have symptoms of an enlarged spleen.

In patients with polycythaemia vera, the body produces too many red blood cells, which can cause the blood to thicken and reduce blood flow to the organs. The patients' spleen may also become larger as it tries to remove excess cells.

Polycythaemia vera is rare, and Besremi was designated an 'orphan medicine' (a medicine used in rare diseases) on 9 December 2011. Further information on the orphan designation can be found here: ema.europa.eu/medicines/human/orphan-designations/EU311932.

Besremi contains the active substance ropeginterferon alfa-2b.

How is Besremi used?

Besremi can only be obtained with a prescription and treatment should only be started under the supervision of a doctor experienced in managing polycythaemia vera.

Besremi is available for injection under the skin in pre-filled pens. The usual starting dose is 100 micrograms every two weeks, which can be increased gradually until the levels of red blood cells are sufficiently low and stable. The maximum dose is 500 micrograms every two weeks. If side effects occur, the doctor can reduce the dose or stop treatment temporarily.

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

How does Besremi work?

The active substance in Besremi, ropeginterferon alfa-2b, works by attaching to receptors (targets) on body cells called interferon alfa/beta receptors (IFNAR). This starts several reactions that cause the bone marrow to produce fewer red blood cells.

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Ropeginterferon alfa-2b is a type of 'interferon', a natural substance produced by the body. In Besremi, the interferon has been 'pegylated' (attached to a chemical called polyethylene glycol) so that it can stay longer in the body and be given less often.

What benefits of Besremi have been shown in studies?

A main study of 257 patients showed that Besremi is effective at reducing levels of red blood cells in patients with polycythaemia vera. In this study, 43% of patients receiving Besremi had normal red blood cell counts after one year of treatment; 46% of patients receiving another medicine, hydroxycarbamide, had similar improvements.

An extension of this study showed that continuing treatment with Besremi for longer increased the number of patients whose blood counts reduced to normal.

What are the risks associated with Besremi?

The most common side effects with Besremi (which may affect more than 1 in 10 people) are low levels of white blood cells and platelets (blood components that help the blood to clot), muscle and joint pain, tiredness, flu-like symptoms and increased blood levels of gamma-glutamyl transferase (a sign of liver problems). For the full list of side effects of Besremi, see the package leaflet.

Besremi must not be used together with telbivudine (a medicine for treating hepatitis B). It must not be used in patients with thyroid disease which is not controlled by standard treatment, patients who have had psychiatric illnesses such as severe depression, patients with severe problems affecting the heart and the blood vessels, patients who have recently had a heart attack or stroke, patients suffering from autoimmune diseases, patients who have had a transplant, and patients with very severe liver or kidney disease. For the full list of restrictions, see the package leaflet.

Why is Besremi authorised in the EU?

Besremi is effective at reducing the excessive number of blood cells in patients with polycythaemia vera, and the proportion of patients improving increased with longer treatment. Although Besremi may be less effective than hydroxycarbamide in the first months of treatment, phlebotomy (a procedure to remove excess blood from the body) can help to control the condition in the short term.

As for its safety, the side effects of Besremi are considered manageable. In addition, the fact that Besremi does not have the potential to cause gene mutations was considered an important benefit. The European Medicines Agency therefore decided that Besremi'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 Besremi?

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

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

Other information about Besremi

Besremi received a marketing authorisation valid throughout the EU on 15 February 2019.

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

This overview was last updated in 04-2019.