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EPAR summary for the public

Yervoy

ipilimumab

This is a summary of the European public assessment report (EPAR) for Yervoy. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Yervoy.

For practical information about using Yervoy, patients should read the package leaflet or contact their doctor or pharmacist.

What is Yervoy and what is it used for?

Yervoy is a medicine that increases the activity of the immune system (the body's natural defences) and is used to treat adults with advanced melanoma (a type of skin cancer affecting cells called melanocytes).

Yervoy contains the active substance ipilimumab.

How is Yervoy used?

Yervoy can only be obtained with a prescription and treatment should be started and supervised by a specialist doctor experienced in treating cancer. The doctor should check the patient's liver and thyroid function before starting treatment and regularly during treatment.

Yervoy is available as a concentrate that is made up into a solution for infusion (drip) into a vein and given over 90 minutes. The patient receives four doses in total, with three weeks between each dose. Doses may need to be delayed if certain side effects occur, and treatment may have to be stopped altogether if side effects are severe. The recommended dose for each infusion is 3 mg per kilogram body weight.

How does Yervoy work?

The active substance in Yervoy, ipilimumab, is a monoclonal antibody. A monoclonal antibody is a type of protein that has been designed to recognise and attach to a specific target on cells in the body.

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Ipilimumab acts on a type of white blood cells called T cells which form part of the immune system. It attaches to and blocks the activity of CTLA-4, a protein that controls the activity of T cells. By blocking CTLA-4, ipilimumab causes activation and increase of T cells, which enter into tumours and kill the tumour cells.

What benefits of Yervoy have been shown in studies?

Two main studies found Yervoy to be effective in improving survival (how long the patients lived).

The first study involved 676 patients with advanced melanoma in whom previous treatment had not worked or had stopped working. The patients received Yervoy (3 mg per kg), or an experimental medicine called 'gp100', or a combination of Yervoy and gp100. Overall survival was around 10 months in patients treated either with Yervoy or the combination which included Yervoy, compared with 6 months in patients receiving gp100 alone.

The second study involved 502 patients with advanced melanoma that had not been treated previously. High-dose Yervoy (10 mg per kg) or placebo (a dummy treatment) was added to standard treatment with dacarbazine, another cancer medicine. The overall survival in patients given Yervoy with dacarbazine was on average 11 months, compared with 9 months in those given placebo plus dacarbazine. However, about one-third of the patients given Yervoy could not complete treatment due to side effects.

A further study involving 727 patients with advanced melanoma compared two doses of Yervoy: 3 mg per kg and 10 mg per kg. The overall survival in patients treated with 3 mg per kg was on average around 12 months compared with 16 months in those treated with 10 mg per kg. However, patients taking the higher dose had more side effects and were more likely not to be able to complete treatment as a result.

In addition, several studies involving previously untreated patients found that overall survival in patients treated with Yervoy at 3 mg per kg was on average 13.5 months.

What are the risks associated with Yervoy?

Yervoy is commonly associated with side effects resulting from excessive activity of the immune system, including severe reactions and inflammation. Most will improve with appropriate treatment or on stopping Yervoy. The most common individual side effects (which may affect more than 1 in 10 people) are diarrhoea, rash, pruritus (itching), fatigue (tiredness), nausea (feeling sick), vomiting, decreased appetite and abdominal pain (stomach ache). For the full list of all side effects reported with Yervoy, see the package leaflet.

Why is Yervoy approved?

The European Medicines Agency noted that Yervoy improves survival in a condition where overall survival rates are low. With regard to the medicine's side effects, the most frequent were mild to moderate in severity. The Agency therefore decided that Yervoy's benefits are greater than its risks and recommended that it be given marketing authorisation. Despite longer survival with a dose of 10 mg per kg, the Agency recommended using Yervoy at a dose of 3 mg per kg because the dose of 10 mg per kg caused more side effects and worsened patients' quality of life after the start of treatment.

What measures are being taken to ensure the safe use of Yervoy?

The company that makes Yervoy must ensure that all healthcare professionals expected to prescribe the medicine as well as patients are provided with a brochure with safety information on the medicine including the side effects related to the excessive activity of the immune system. Patients will also receive from their doctor an alert card summarising key safety information on the medicine.

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

Other information about Yervoy

The European Commission granted a marketing authorisation valid throughout the European Union for Yervoy on 13 July 2011.

The full EPAR for Yervoy can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Yervoy, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 12-2017.