



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/536607/2017
EMA/H/C/002532

EPAR summary for the public

Zaltrap

aflibercept

This is a summary of the European public assessment report (EPAR) for Zaltrap. 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 Zaltrap.

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

What is Zaltrap and what is it used for?

Zaltrap is a cancer medicine used to treat adults with metastatic colorectal cancer (cancer of the large bowel that has spread to other parts of the body) for whom treatment based on another medicine, oxaliplatin, has not worked or the cancer got worse. Zaltrap is used with FOLFIRI, which is a treatment combining the medicines irinotecan, 5-fluorouracil, and folinic acid.

The medicine contains the active substance aflibercept.

How is Zaltrap used?

Zaltrap can only be obtained with a prescription and treatment should be supervised by a doctor who is experienced in using cancer medicines.

Zaltrap is given as an infusion (drip) into the vein over one hour, at a dose of 4 mg per kilogram body weight. This is then followed by the FOLFIRI treatment. This cycle of treatment is repeated every two weeks, until the disease gets worse or the patient cannot tolerate the treatment. Treatment should be discontinued, delayed, or the dose may have to be adjusted, in patients who develop certain side effects. For further details, see the package leaflet.



How does Zaltrap work?

The active substance in Zaltrap, aflibercept, is a protein that attaches to vascular endothelial growth factor (VEGF) and placenta growth factor (PlGF), substances that circulate in the blood and make blood vessels grow. By binding to VEGF and PlGF, aflibercept stops them having an effect. As a result, the cancer cells cannot develop their own blood supply and are starved of oxygen and nutrients, so helping to slow down the growth of tumours.

What benefits of Zaltrap have been shown in studies?

Zaltrap was investigated in one main study involving 1,226 adults with metastatic colorectal cancer that had not responded to oxaliplatin-based treatment. Zaltrap was compared with placebo (a dummy treatment) when added to FOLFIRI. The main measure of effectiveness was the average length of time that patients survived after treatment.

In this study, Zaltrap was more effective than placebo at increasing survival of patients: patients treated with Zaltrap plus FOLFIRI lived an average of 13.5 months, whereas patients treated with placebo and FOLFIRI lived an average of 12.1 months.

What are the risks associated with Zaltrap?

The most common side effects with Zaltrap in combination with FOLFIRI (which may affect more than 20 patients in 100) are leucopenia and neutropenia (low levels of white cells in the blood, including the type that fight infections), diarrhoea, proteinuria (protein in the urine), increased blood levels of liver enzymes (aspartate and alanine transaminases), stomatitis (inflammation of the mouth), tiredness, thrombocytopenia (low blood platelet counts), hypertension (high blood pressure), weight loss, decreased appetite, epistaxis (nose bleeds), abdominal pain, dysphonia (speech disturbance), increases in creatinine in the blood (a marker of kidney problems), and headache. The most common effects that led to treatment being permanently stopped were problems with the circulation including hypertension, infections, tiredness, diarrhoea, dehydration, stomatitis, neutropenia, proteinuria, and pulmonary embolism (a clot in a blood vessel supplying the lungs).

For the full list of all side effects reported with Zaltrap, see the package leaflet.

Although medicines containing the same active substance are available for injection into the eye, Zaltrap must not be injected into the eye as it was not developed for such use and may cause local damage. For the full list of restrictions, see the package leaflet.

Why is Zaltrap approved?

Although Zaltrap is associated with significant side effects, which can be severe enough to force treatment to be stopped, the results of the large main study show that there is a small but clinically significant benefit in prolonging the life of treated patients in whom previous treatment failed. Overall, the European Medicines Agency decided that Zaltrap's benefits are greater than its risks and recommended that it be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Zaltrap?

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

Other information about Zaltrap

The European Commission granted a marketing authorisation valid throughout the European Union for Zaltrap on 1 February 2013.

The full EPAR for Zaltrap 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 Zaltrap, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2017.