EMA/364550/2015
EMEA/H/C/002800

EPAR summary for the public

Unituxin

dinutuximab

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

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

What is Unituxin and what is it used for?

Unituxin is a cancer medicine used to treat neuroblastoma, a nerve cell cancer, in children aged 12 months to 17 years.

Unituxin is used to treat children with 'high-risk' neuroblastoma, the form of the cancer that has a high chance of returning. Children treated with Unituxin will first have responded to chemotherapy and then received an additional treatment to clear out their bone marrow (myeloablative therapy) and a stem-cell transplantation.

Unituxin is given in combination with 3 other medicines: GM-CSF, interleukin-2 and isotretinoin.

Because the number of patients with neuroblastoma is low, the disease is considered 'rare', and Unituxin was designated an 'orphan medicine' (a medicine used in rare diseases) on 21 June 2011.

Unituxin contains the active substance dinutuximab.

How is Unituxin used?

Unituxin is given as an infusion (drip) into a vein. The daily dose depends on the child's body surface area, and infusions are given over 10 hours. The patient also receives 3 other medicines: isotretinoin,

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GM-CSF and interleukin-2. Treatment lasts around 6 months, but not all the medicines are given every month. Unituxin is given on four consecutive days each month, in the first 5 months.

Because of the risk of severe allergic reactions with Unituxin, equipment and staff should be immediately available to resuscitate the patient if reactions occur. Patients should also be given an antihistamine medicine before the start of each Unituxin infusion to reduce the risk of a reaction.

Because pain is a common side of Unituxin treatment, patients are also given pain killers.

Unituxin is only for hospital use and treatment should be supervised by a doctor experienced in cancer treatments. The medicine can only be obtained with a prescription.

How does Unituxin work?

The active substance in Unituxin, dinutuximab, is a monoclonal antibody, designed to recognise and attach to a substance present at high levels in neuroblastoma cancer cells known as ganglioside GD2. When dinutuximab attaches to the gangliosides on neuroblastoma cells, it marks the cells out as targets for the immune system (the body's natural defences), which then attacks them. In this way, the medicine can help clear out cancer cells remaining in the body following other treatments.

What benefits of Unituxin have been shown in studies?

A main study conducted in 230 patients with high-risk neuroblastoma showed that Unituxin (given with isotretinoin, GM-CSF and interleukin-2) was more effective than isotretinoin alone at keeping patients alive and preventing the re-emergence of their cancer. After around 3 years, 80% of patients receiving Unituxin were alive compared with 67% of patients receiving isotretinoin alone.

What are the risks associated with Unituxin?

The most common side effects with Unituxin (seen in more than 30% of patients) are: pain affecting any part of the body, hypotension (low blood pressure), hypersensitivity (allergic reactions), fever, urticaria (hives), capillary leak syndrome (a condition whereby fluid leaks from the blood vessels causing swelling and a fall in blood pressure), anaemia (low red blood cell counts), low platelet counts, low sodium and potassium levels, raised liver enzymes and low levels of white blood cells. For the full list of all side effects and restrictions, see the package leaflet.

Why is Unituxin approved?

Patients with high-risk neuroblastoma need aggressive therapy, which is often not sufficient to prevent the cancer from returning. A study of Unituxin in combination with isotretinoin, GM-CSF and interleukin-2 showed that the combination can improve outcomes in these patients, keeping them alive for longer and helping to prevent the disease from returning or getting worse.

Although side effects with Unituxin can be severe, and medication is required to prevent allergic reactions and pain, the medicine's risks are considered acceptable given the severity of the disease. The number of patients who have to stop treatment because of side effects appears low and the side effects can be managed with appropriate measures.

The Agency's Committee for Medicinal Products for Human Use (CHMP) therefore concluded that Unituxin'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 Unituxin?

A risk management plan has been developed to ensure that Unituxin is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Unituxin, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets Unituxin will carry out two studies to get more information about the safety of the medicine, including its long-term safety.

Further information can be found in the summary of the risk management plan.

Other information about Unituxin

The European Commission granted a marketing authorisation valid throughout the European Union for Unituxin on 14 August 2015.

The full EPAR and risk management plan summary for Unituxin 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 Unituxin, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Unituxin can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 08-2015.