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SCIENCE MEDICINES HEALTH

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Sylvant (*siltuximab*)

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

What is Sylvant and what is it used for?

Sylvant is a medicine that is used to treat multicentric Castleman's disease in adults who are not infected with human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8).

Castleman's disease is a disorder of the lymphatic system (a network of vessels that transport fluid from tissues through the lymph nodes and into the bloodstream) in which cells in lymph nodes start growing abnormally, causing benign tumours. Multicentric means that the disease affects several lymph nodes as well as other organs in the body. Symptoms can include tiredness, sweating at night, fever, peripheral neuropathy (pins and needles due to nerve damage) and swelling of liver and spleen.

Castleman's disease is rare, and Sylvant was designated an 'orphan medicine' (a medicine used in rare diseases) on 30 November 2007. Further information on the orphan designation can be found here: [ema.europa.eu/Find medicine/Human medicines/Rare disease designation](http://ema.europa.eu/Find%20medicine/Human%20medicines/Rare%20disease%20designation).

Sylvant contains the active substance siltuximab.

How is Sylvant used?

Sylvant can only be obtained with a prescription and treatment should be given by qualified healthcare professionals and under appropriate medical supervision. It is given by infusion (drip) into a vein. The recommended dose is 11 mg per kilogram body weight, and the infusion should last around one hour. Sylvant is given every three weeks, until the patient no longer benefits from treatment.

During the first 12 months of treatment the patient should have a blood test before each dose of Sylvant, and every nine weeks afterwards; treatment may need to be delayed in patients whose blood tests are abnormal or who have certain side effects.

For more information about using Sylvant, see the summary of product characteristics or contact a doctor or pharmacist.

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How does Sylvant work?

The active substance in Sylvant, siltuximab, is a monoclonal antibody. A monoclonal antibody is a type of protein that has been designed to recognise and attach to a specific structure (called an antigen) in the body. Siltuximab has been designed to attach to a protein in the body called interleukin 6 (IL-6). Patients with Castleman's disease produce too much IL-6 and this is thought to contribute to the abnormal growth of certain cells in the lymph nodes. By attaching to IL-6, siltuximab blocks its activity and stops abnormal cell growth, thus reducing the size of the lymph nodes and the symptoms of the disease.

What benefits of Sylvant have been shown in studies?

Sylvant has been investigated in one main study involving 79 adults with multicentric Castleman's disease who did not have HIV or HHV-8 infection. The effect of the medicine was compared with placebo (a dummy treatment) and the main measure of effectiveness was the proportion of patients who responded to treatment for at least 18 weeks, as shown by a 50% reduction ('partial response') or complete disappearance ('complete response') of tumours and symptoms of the disease.

Sylvant was more effective than placebo in reducing tumour size and disease symptoms: 17 out of 53 patients who received Sylvant showed a partial response and one showed a complete response, compared with none of the 26 patients who received placebo. This effect was maintained for almost one year.

What are the risks associated with Sylvant?

The most common side effects with Sylvant (which may affect more than 1 in 5 people) are infections (including upper respiratory tract infections such as those of the throat and nose), itching, rash, joint pain and diarrhoea. The most serious side effect is anaphylactic reaction (a severe allergic reaction).

For the full list of side effects and restrictions of Sylvant, see the package leaflet.

Why is Sylvant authorised in the EU?

The European Medicines Agency decided that Sylvant's benefits are greater than its risks and it can be authorised for use in the EU. The Agency concluded that Sylvant has shown beneficial effect by reducing tumour size and symptoms in patients with multicentric Castleman's disease, and that this positive effect seems to be maintained over time. The Agency also acknowledged that there is an unmet medical need for these patients. Side effects of Sylvant were considered acceptable but further long-term data are to be collected.

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

The company that markets Sylvant is required to set up a patient registry to provide further data on long-term safety. The company will ensure that healthcare professionals who are expected to use the medicine are provided with information on how to enter their patients in the registry.

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

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

Other information about Sylvant

Sylvant received a marketing authorisation valid throughout the EU on 22 May 2014.

Further information on Sylvant can be found on the Agency's website: ema.europa.eu/Find/medicine/Human_medicines/European_public_assessment_reports.

This overview was last updated in 06-2018.