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Nordimet (*methotrexate*)

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

What is Nordimet and what is it used for?

Nordimet is a medicine used to treat the following inflammatory conditions:

- active rheumatoid arthritis, a disease causing inflammation in joints;
- severe juvenile idiopathic arthritis (JIA), a joint disease in children, when medicines known as NSAIDs (non-steroidal anti-inflammatory drugs) have not worked well enough;
- severe disabling psoriasis, a disease causing red, scaly patches on the skin, when other treatments have not worked well enough;
- severe psoriatic arthritis, inflammation of the joints that occurs in patients with psoriasis.

Nordimet contains the active substance methotrexate.

Nordimet is a 'hybrid medicine'. This means that it is similar to a 'reference medicines' containing the same active substance, but Nordimet is available in more strengths. The reference medicine for Nordimet is Lantarel FS.

How is Nordimet used?

Nordimet is available as various strengths of injection and it can only be obtained with a prescription. It should be prescribed only by doctors with expertise in the use of methotrexate and a full understanding of the risks of methotrexate treatment.

Nordimet should be injected under the skin once a week on the same day each week. The dose injected each week depends on which condition it is being used for and how well the treatment is working and, for children, on the child's height and weight. In most cases, methotrexate medicines are used for long-term treatment.

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

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How does Nordimet work?

The way methotrexate, the active substance in Nordimet, works in patients with arthritis and psoriasis is not completely understood, but the benefits of methotrexate are thought to be due to its ability to reduce inflammation and suppress an overactive immune system.

What benefits of Nordimet have been shown in studies?

The company provided data from the published literature on methotrexate. No additional studies were needed as Nordimet is a hybrid medicine that is given by injection and contains the same active substance as the reference medicine, Lantarel FS. Because Nordimet has the same composition as the reference medicine its benefits are taken as being the same as those of Lantarel FS.

What are the risks associated with Nordimet?

The most common side effects with Nordimet (which may affect more than 1 in 10 people) are effects in the digestive system (such as inflammation of the lining of the mouth, indigestion, belly pain, feeling sick and loss of appetite) and blood tests showing changes in the liver. The most serious side effects include reduced production of blood cells, damage to the lung, liver, kidneys and nerves, thromboembolism (problems caused by clots in blood vessels), and severe allergic and skin reactions.

Nordimet must not be used in patients who abuse alcohol or those with liver or severe kidney problems, blood disorders, weakened immune system (body defences), severe or long-term infections such as tuberculosis and HIV infection, mouth ulcers, inflammation in the mouth, and ulcers in the digestive system. It must not be used if the patient is pregnant, breastfeeding or is receiving live vaccines.

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

Why is Nordimet authorised in the EU?

The European Medicines Agency concluded that Nordimet was comparable to its reference medicine. The Agency therefore decided that Nordimet'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 Nordimet?

The company that markets Nordimet will send out follow-up questionnaires for dosing errors that result in overdose.

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

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

Other information about Nordimet

Nordimet received a marketing authorisation valid throughout the EU on 18 August 2016.

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

This overview was last updated in 10-2019.