EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 June 2016
EMA/CHMP/403945/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Nordimet

methotrexate

On 23 June 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Nordimet, intended for the treatment of active rheumatoid arthritis, juvenile idiopathic arthritis, and severe psoriatic arthritis. The applicant for this medicinal product is Nordic Group B.V.

Nordimet will be available as a solution for injection (7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 22.5 mg and 25 mg). The active substance of Nordimet is methotrexate, an anti-metabolite folic acid analogue (ATC code: L01BA01) which inhibits DNA synthesis through the competitive inhibition of the enzyme dihydrofolate reductase.

The benefits with Nordimet are its ability to reduce the symptoms of rheumatoid arthritis, psoriasis and psoriatic arthritis. The most common side effects are abnormal liver function tests, stomatitis, dyspepsia, nausea, abdominal pain and loss of appetite.

Nordimet is a hybrid of Lantarel FS (25 mg solution for injection), a medicine containing the same active substance that has been authorised in Germany since 1992.

The full indication is:

“Nordimet is indicated for the treatment of:

- active rheumatoid arthritis in adult patients,
- polyarthritic forms of severe, active juvenile idiopathic arthritis (JIA), when the response to nonsteroidal anti-inflammatory drugs (NSAIDs) has been inadequate,
- severe recalcitrant disabling psoriasis, which is not adequately responsive to other forms of therapy such as phototherapy, PUVA, and retinoids, and severe psoriatic arthritis in adult patients.”

It is proposed that Nordimet be prescribed by physicians with experience in the various properties of the medicinal product and its mode of action.

Detailed recommendations for the use of this product will be described in the summary of product

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.