26 January 2017
EMA/CHMP/15894/2017 Rev 1
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Jylamvo

methotrexate

On 26 January 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Jylamvo, intended for the treatment of rheumatological disorders and psoriasis and for the maintenance treatment of acute lymphoblastic leukaemia (ALL). The applicant for this medicinal product is Therakind Limited.

Jylamvo will be available as an oral solution (2 mg/ml). The active substance of Jylamvo is methotrexate, an antineoplastic and immunomodulating agent (ATC code: L01BA01). Methotrexate is a folic acid antagonist that acts by competitive inhibition of the enzyme dihydrofolate reductase and thus inhibits DNA synthesis, resulting in anti-inflammatory, immunosuppressive and cytotoxic effects. Highly proliferating tissues such as malignant cells, bone marrow, fetal cells, skin epithelium and mucosa are more sensitive to methotrexate than normal tissues.

The benefits with Jylamvo are its ability to reduce the symptoms of rheumatoid arthritis, severe juvenile idiopathic arthritis, psoriasis and psoriatic arthritis and to exert a sustained effect on malignant growth in ALL. The most common side effects are abnormal liver function tests, stomatitis, dyspepsia, nausea, abdominal pain and loss of appetite.

Jylamvo is a hybrid medicine[2] of Methotrexat “Lederle” 25 mg-Stechampulle and Methotrexate “Lederle” 2.5 mg tablets which have been authorised in the EU since 1984 and 1959 respectively. Jylamvo contains the same active substance as these reference medicines but is given by mouth as a solution. Studies have demonstrated the satisfactory quality of Jylamvo and its bioequivalence to Methotrexate “Lederle” 2.5 mg tablets and a third product, Ebetrexat 10 mg tablets which is authorised in similar indications.

The full indication is:

"Jylamvo is for use in the following indications:

<u>In rheumatological and dermatological diseases</u>

[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

[2] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Active rheumatoid arthritis in adult patients.

Polyarthritic forms of active, severe juvenile idiopathic arthritis (JIA) in adolescents and children aged 3 years and over when the response to non-steroidal anti-inflammatory drugs (NSAIDs) has been inadequate.

Severe, treatment-refractory, disabling psoriasis which does not respond sufficiently to other forms of treatment such as phototherapy, psoralen and ultraviolet A radiation (PUVA) therapy and retinoids, and severe psoriatic arthritis in adult patients.

In oncology

Maintenance treatment of acute lymphoblastic leukaemia (ALL) in adults, adolescents and children aged 3 years and over."

It is proposed that Jylamvo be prescribed by physicians with experience of 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 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.