30 January 2020
EMA/CHMP/28370/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Arsenic trioxide Mylan

arsenic trioxide

On 30 January 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Arsenic trioxide Mylan, intended for the treatment of acute promyelocytic leukaemia (APL). The applicant for this medicinal product is Mylan Ireland Limited.

Arsenic trioxide Mylan will be available as 1 mg/ml concentrate for solution for infusion. The active substance of Arsenic trioxide Mylan is arsenic trioxide, an antineoplastic agent (ATC code: L01XX27) that causes fragmentation, damage or degradation of deoxyribonucleic acid (DNA) and the fusion protein pro-myelocytic leukaemia/retinoic acid receptor-alpha (PML/RAR alpha) in promyelocytic leukaemia cells. The mechanism of action of arsenic trioxide is not completely understood.

Arsenic trioxide Mylan is a generic of Trisenox, which has been authorised in the EU since 5 March 2002. Since Arsenic trioxide Mylan is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product Trisenox was not required. A question and answer document on generic medicines can be found here.

The full indication is:

> "Arsenic trioxide Mylan is indicated for induction of remission, and consolidation in adult patients with:
>
> - Newly diagnosed low-to-intermediate risk acute promyelocytic leukaemia (APL) (white blood cell count, ≤ 10 x 10^3/µl) in combination with all-*trans*-retinoic acid (ATRA)
> - Relapsed/refractory acute promyelocytic leukaemia (APL) (Previous treatment should have included a retinoid and chemotherapy)
>
> characterised by the presence of the t(15;17) translocation and/or the presence of the Pro-Myelocytic Leukaemia/Retinoic-Acid-Receptor-alpha (PML/RAR-alpha) gene.
>
> The response rate of other acute myelogenous leukaemia subtypes to arsenic trioxide has not been examined."

[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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It is proposed that Arsenic trioxide Mylan be prescribed by physicians experienced in the treatment of acute leukaemias.

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.