19 September 2019
EMA/CHMP/498421/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Arsenic trioxide Accord

arsenic trioxide

On 19 September 2019, 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 Accord, intended for the treatment of acute promyelocytic leukaemia (APL). The applicant for this medicinal product is Accord Healthcare S.L.U.

Arsenic trioxide Accord will be available as a 1 mg/ml concentrate for solution for infusion. The active substance of Arsenic trioxide Accord 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 Accord is a generic of Trisenox, which has been authorised in the EU since 5 March 2002. Since Arsenic trioxide Accord 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 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 103/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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

It is proposed that Arsenic trioxide Accord be prescribed by physicians experienced in the management 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.