EMA/520484/2019
EMEA/H/C/005175

Arsenic trioxide Accord (*arsenic trioxide*)

An overview of Arsenic trioxide Accord and why it is authorised in the EU

What is Arsenic trioxide Accord and what is it used for?

Arsenic trioxide Accord is used to treat adults (aged 18 years or over) with acute promyelocytic leukaemia (APL), a rare form of leukaemia (cancer of the white blood cells) caused by a genetic 'translocation' (when there is a swap of genes between two chromosomes). The translocation affects the way the white blood cells grow, and as a result they lack the ability to use retinoic acid (vitamin A). Patients with APL are normally treated with retinoids (substances derived from vitamin A).

Arsenic trioxide Accord is used in:

- Patients with newly diagnosed low or intermediate risk APL where it is used together with the medicine all-trans-retinoic acid.
- Patients with APL whose disease has not responded to previous treatment with a retinoid and cancer medicines, or when their disease has come back after this type of treatment.

Arsenic trioxide Accord contains the active substance arsenic trioxide and is a 'generic medicine'. This means that Arsenic trioxide Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Trisenox. For more information on generic medicines, see the question-and-answer document here.

How is Arsenic trioxide Accord used?

Arsenic trioxide Accord can only be obtained with a prescription and its use should be supervised by a doctor who has experience in the management of patients with acute leukaemias. It is given as an infusion (drip) into a vein. The infusion should last 1 to 2 hours, but it may need to be given for longer if the patient has certain side effects.

The recommended dose of Arsenic trioxide Accord depends on the patient's weight. Treatment is divided into 2 phases: induction and consolidation.

During the induction phase, Arsenic trioxide Accord is given every day until there are signs that the treatment is working (when the bone marrow does not contain any leukaemia cells). If this does not happen by day 50 (for previously treated patients) or by day 60 (for newly diagnosed patients), the treatment should be stopped.

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During the consolidation phase, Arsenic trioxide Accord is given on 5 days each week but the length of breaks between courses and how long it is given for depends on whether patients have received previous treatment or not.

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

How does Arsenic trioxide Accord work?

The active substance in the medicine, arsenic trioxide, has been used in medicines for many years, including for the treatment of leukaemia. The way it works in this disease is not completely understood. It is thought to prevent the production of DNA, which is necessary for leukaemia cells to grow.

How has Arsenic trioxide Accord been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Trisenox, and do not need to be repeated for Arsenic trioxide Accord.

As for every medicine, the company provided studies on the quality of Arsenic trioxide Accord. There was no need for 'bioequivalence' studies to investigate whether Arsenic trioxide Accord is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Arsenic trioxide Accord is given by infusion into a vein, so the active substance is delivered straight into the bloodstream.

What are the benefits and risks of Arsenic trioxide Accord?

Because Arsenic trioxide Accord is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Arsenic trioxide Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Arsenic trioxide Accord has been shown to be comparable to Trisenox. Therefore, the Agency's view was that, as for Trisenox, the benefits of Arsenic trioxide Accord outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Arsenic trioxide Accord?

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

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

Other information about Arsenic trioxide Accord

Arsenic trioxide Accord received a marketing authorisation valid throughout the EU on 14 November 2019.

Further information on Arsenic trioxide Accord can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/arsenic-trioxide-accord. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 11-2019.