EMA/407447/2020
EMEA/H/C/005218

Arsenic trioxide medac (*arsenic trioxide*)

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

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

Arsenic trioxide medac is used to treat adults (aged 18 years or over) with acute promyelocytic leukaemia (APL).

APL is 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 medac is used in:

- patients with newly diagnosed low or intermediate risk APL where it is used together with the medicine all-trans-retinoic acid (ATRA);
- 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 medac is a 'generic medicine'. This means that Arsenic trioxide medac 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.

Arsenic trioxide medac contains the active substance arsenic trioxide.

How is Arsenic trioxide medac used?

Arsenic trioxide medac can only be obtained with a prescription and treatment should be supervised by a doctor who has experience in the management of patients with acute leukaemias. The medicine is given by infusion (drip) into a vein. The infusion should last one to two hours, but the doctor may have to slow it down if the patient has certain side effects.

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

During the induction phase, Arsenic trioxide medac is given every day until there are signs that the treatment is working (when the bone marrow no longer contains any leukaemia cells). If this does not

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happen by day 50 (for previously treated patients) or by day 60 (for newly diagnosed patients), the treatment should be stopped.

During the consolidation phase, Arsenic trioxide medac is given once a day for five days, followed by a two-day break, repeated for four or five weeks. The number of times these cycles are repeated depends on whether patients have received previous treatment or not.

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

How does Arsenic trioxide medac work?

The active substance in Arsenic trioxide medac, arsenic trioxide, is a chemical that 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 (genetic material), which is necessary for leukaemia cells to grow.

How has Arsenic trioxide medac 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 medac.

As for every medicine, the company provided studies on the quality of Arsenic trioxide medac. There was no need for 'bioequivalence' studies to investigate whether Arsenic trioxide medac is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Arsenic trioxide medac 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 medac?

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

Why is Arsenic trioxide medac authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Arsenic trioxide medac has been shown to be comparable to Trisenox. Therefore, the Agency's view was that, as for Trisenox, the benefits of Arsenic trioxide medac 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 medac?

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

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

Other information about Arsenic trioxide medac

Arsenic trioxide medac received a marketing authorisation valid throughout the EU on 17 September 2020.

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

This overview was last updated in 09-2020.