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Arsenic trioxide Mylan (*arsenic trioxide*)

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

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

Arsenic trioxide Mylan 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 Mylan 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 Mylan is a 'generic medicine'. This means that Arsenic trioxide Mylan 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 Mylan contains the active substance arsenic trioxide.

How is Arsenic trioxide Mylan used?

Arsenic trioxide Mylan 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. It is available as a concentrate that is made up into a solution for infusion (drip) into a vein. The infusion should last one to two hours, but it may last longer if the patient has certain side effects.

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

During the induction phase, Arsenic trioxide Mylan 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

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

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 Mylan 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 Mylan, see the package leaflet or contact your doctor or pharmacist.

How does Arsenic trioxide Mylan work?

The active substance in Arsenic trioxide Mylan, 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, which is necessary for leukaemia cells to grow.

How has Arsenic trioxide Mylan been studied?

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

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

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

Why is Arsenic trioxide Mylan authorised in the EU?

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

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

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

Other information about Arsenic trioxide Mylan

Arsenic trioxide Mylan received a marketing authorisation valid throughout the EU on 01 April 2020.

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

This overview was last updated in 03-2020.