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EPAR summary for the public

Trisenox

arsenic trioxide

This is a summary of the European public assessment report (EPAR) for Trisenox. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Trisenox.

For practical information about using Trisenox, patients should read the package leaflet or contact their doctor or pharmacist.

What is Trisenox and what is it used for?

Trisenox 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).

Trisenox 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.

Trisenox contains the active substance arsenic trioxide.

How is Trisenox used?

Trisenox 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.

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

During the induction phase, Trisenox 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.

During the consolidation phase, Trisenox 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 further information, see the package leaflet.

How does Trisenox work?

The active substance in Trisenox, 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.

What benefits of Trisenox have been shown in studies?

Trisenox has been investigated in 159 newly diagnosed patients who had not yet received any treatment for APL. Trisenox was compared with an anthracycline (a type of cancer medicine), both taken in combination with ATRA, and the measure of effectiveness was the number of patients who did not experience any event (such as worsening of their disease or death) 2 years after diagnosis. 97% (72 out of 74) of patients treated with Trisenox did not have any event, compared with 86% (65 out of 76) of those treated with anthracyclines.

Trisenox has also been investigated in two studies involving a total of 52 patients with APL who had been previously treated with an anthracycline and a retinoid. Forty-five of the patients in the studies were adults. Trisenox was not compared with any other medicine in either study. The main measure of effectiveness was the number of patients who had complete remission. This is when there are no more leukaemia cells in the bone marrow and the levels of platelets and white blood cells in the blood have recovered. Looking at the results of these two studies together, 87% of the patients had complete remission (45 out of 52). On average, it took 57 days for the patients to reach complete remission.

What are the risks associated with Trisenox?

The most common side effects with Trisenox (seen in 1 patient in 10) are hyperglycaemia (high blood glucose levels), hypomagnesaemia (low blood magnesium levels), hypokalaemia (low blood potassium levels), paraesthesia (unusual sensations like pins and needles), dizziness, headache, tachycardia (rapid heartbeat), dyspnoea (difficulty breathing), differentiation syndrome (a potentially fatal complication of chemotherapy in patients with APL), diarrhoea, vomiting, nausea (feeling sick), pruritus (itching), rash, myalgia (muscle pain), pyrexia (fever), pain, fatigue (tiredness), oedema (swelling), prolonged QT interval on an electrocardiogram (an alteration of the electrical activity of the heart), and increased levels of alanine aminotransferase and aspartate aminotransferase (liver enzymes). For the full list of all side effects and restrictions with Trisenox, see the package leaflet.

Why is Trisenox approved?

The CHMP decided that Trisenox's benefits are greater than its risks and recommended that it be given marketing authorisation.

Trisenox was originally authorised under 'exceptional circumstances', because, as the disease is rare, limited information was available at the time of approval. As the company had supplied the additional information requested, the 'exceptional circumstances' ended on 10 August 2010.

What measures are being taken to ensure the safe and effective use of Trisenox?

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

Other information about Trisenox

The European Commission granted a marketing authorisation valid throughout the European Union for Trisenox on 5 March 2002.

The full EPAR for Trisenox can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Trisenox, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2016.