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EPAR summary for the public

ATryn

antithrombin alfa

This document is a summary of the European Public Assessment Report (EPAR) for ATryn. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for ATryn.

What is ATryn?

ATryn is a powder that is made up into a solution for infusion (drip) into a vein. It contains the active substance antithrombin alfa.

What is ATryn used for?

ATryn is used in adults who have 'congenital antithrombin deficiency' (inherited low levels of the protein antithrombin). It is used when the patients are having surgery, to prevent problems due to the formation of blood clots. ATryn is normally given with heparin (another medicine that helps to prevent blood clots).

The medicine can only be obtained with a prescription.

How is ATryn used?

Treatment with ATryn should only be started by doctors who are experienced in treating patients with congenital antithrombin deficiency. The doctor needs to calculate the doses to use, based both on the patient's weight and on the level of antithrombin activity.

The first infusion lasts 15 minutes. This is followed by a continuous infusion at a lower dose, during which the patients should be continually monitored and the infusion rate adjusted, so that the antithrombin activity is at least 80% of the normal level for the duration of treatment. See the package leaflet for full instructions.

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How does ATryn work?

ATryn is an anticlotting agent. The active substance in ATryn, antithrombin alfa, is a copy of the natural blood protein antithrombin, which is produced by 'recombinant DNA technology': it is extracted from the milk of goats that have had a gene (DNA) inserted, which makes them able to produce the human protein in their milk.

In the body, antithrombin blocks thrombin, a substance that plays a central role in the process of blood clotting. Patients who have congenital antithrombin deficiency have low blood antithrombin levels and are therefore at increased risk of having blood clots. ATryn corrects the antithrombin deficiency, and gives temporary control of the clotting disorder.

How has ATryn been studied?

One study of ATryn was carried out in 14 patients aged between 21 and 74 years who had congenital antithrombin deficiency and were at risk of blood clot formation either during surgery (five patients) or during childbirth (nine patients). The studies measured how many patients developed deep vein thrombosis (DVT, formation of a blood clot in a deep vein, usually in the leg) during the 30 days after treatment. Few patients were treated during the study because congenital antithrombin deficiency is rare - it is estimated that only about one person in 3,000 to 5,000 has the condition.

In addition, ATryn was used in five patients who received the medicine during surgery in a 'compassionate-use programme' (a programme through which doctors can request a medicine for one of their patients before it is authorised).

What benefit has ATryn shown during the studies?

In the study, among the 13 patients in whom the effectiveness of the treatment could be assessed, two had an episode of DVT, of which only one needed treatment. In the compassionate-use programme, no blood clots were seen in the patients receiving ATryn. Taken together, the results support the effectiveness of ATryn in preventing blood clot development in patients having surgery. However, there was not enough information to identify the most appropriate dose to use during childbirth.

What is the risk associated with ATryn?

In studies, the most common side effects with ATryn (seen in between 1 and 10 patients in 100) were dizziness, headache, haemorrhage (bleeding, including bleeding at the site of the injection or after surgery), nausea (feeling sick) and wound secretion (discharge from the surgical wound).

ATryn must not be used in people who may be hypersensitive (allergic) to goat proteins or goat milk. Because ATryn is a protein given by injection, patients could develop antibodies (proteins produced in response to the medicine), with a risk of an allergic reaction at the time of injection. However, this has not yet been seen in patients treated with ATryn. For the full list of side effects and restrictions with ATryn, see the package leaflet.

Why has ATryn been approved?

The CHMP concluded that the information provided by the company had shown that ATryn can bring the antithrombin activity up to an acceptable level when used at the recommended dose during surgery. The Committee decided that ATryn's benefits are greater than its risks and recommended that it be given marketing authorisation.

ATryn has been authorised under 'exceptional circumstances'. This means that because the disease is rare, it has not been possible to obtain complete information about ATryn. Every year, the European Medicines Agency will review any new information that may become available and this summary will be updated as necessary.

What information is still awaited for ATryn?

The company that makes ATryn has provided the results of a study looking at the use of ATryn during childbirth in women with congenital antithrombin deficiency to the Agency, and will submit an application with the aim of adding treatment during childbirth to the medicine's marketing authorisation. The company will also put in place, before launch in any European Union (EU) Member State, programmes to ensure that doctors can report information on the patients they treat and monitor the development of antibodies against ATryn.

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

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

Other information about ATryn:

The European Commission granted a marketing authorisation valid throughout the EU for ATryn on 28 July 2006.

The full EPAR for ATryn 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 ATryn, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 06-2016.