EMA/404586/2013
EMEA/H/C/002329

EPAR summary for the public

Atosiban SUN

atosiban

This is a summary of the European public assessment report (EPAR) for Atosiban SUN. 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 Atosiban SUN.

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

What is Atosiban SUN and what is it used for?

Atosiban SUN is a medicine that contains the active substance atosiban. It is used to delay birth in adult women who are 24 to 33 weeks pregnant, when they show signs that they may give birth pre-term (prematurely). These signs include:

- regular contractions lasting at least 30 seconds at a rate of at least four every 30 minutes;
- dilation of the cervix (the neck of the womb) of 1 to 3 cm and an effacement (a measure of the thinness of the cervix) of 50% or more.

In addition, the baby must have a normal heart rate.

Atosiban SUN is a 'generic medicine'. This means that Atosiban SUN is similar to a 'reference medicine' already authorised in the European Union (EU) called Tractocile. For more information on generic medicines, see the question-and-answer document here.

How is Atosiban SUN used?

Atosiban SUN can only be obtained with a prescription. Treatment with Atosiban SUN should be carried out by a doctor who has experience in the treatment of pre-term labour.

Treatment should be started as soon as possible after diagnosis of pre-term labour. Atosiban SUN is available as a solution for injection and as a concentrate that is made up into a solution for infusion

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(drip) into a vein. It is given into a vein in three stages, over a maximum of 48 hours: an initial injection into a vein (6.75 mg), followed by a high-dose infusion (18 mg per hour) over three hours, then a lower dose infusion (6 mg per hour) lasting up to 45 hours. If contractions come back, treatment with Atosiban SUN can be repeated up to three more times during the pregnancy.

How does Atosiban SUN work?

The active substance in Atosiban SUN, atosiban, is an antagonist of the natural hormone oxytocin. This means that atosiban blocks the action of oxytocin. Oxytocin is the hormone involved in starting contractions of the womb. By blocking the action of oxytocin, Atosiban SUN prevents contractions and causes the womb to relax, helping to delay birth.

How has Atosiban SUN been studied?

The company provided data from the published literature on atosiban. No additional studies were needed as Atosiban SUN is a generic medicine that is given by infusion or injection and contains the same active substance as the reference medicine, Tractocile.

What are the benefits and risks of Atosiban SUN?

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

Why is Atosiban SUN approved?

The CHMP concluded that, in accordance with EU requirements, Atosiban SUN has been shown to have comparable quality and to be comparable to Tractocile. Therefore, the CHMP's view was that, as for Tractocile, the benefit outweighs the identified risk. The Committee recommended that Atosiban SUN be given marketing authorisation.

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

A risk management plan has been developed to ensure that Atosiban SUN is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Atosiban SUN, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Atosiban SUN

The European Commission granted a marketing authorisation valid throughout the European Union for Atosiban SUN on 31 July 2013.

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

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 07-2013.