Package leaflet: Information for the user

Atosiban SUN 37.5 mg/5 ml concentrate for solution for infusion
atosiban

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, midwife or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Atosiban SUN is and what it is used for

Atosiban SUN contains atosiban. Atosiban SUN is used to delay the premature birth of your baby. Atosiban SUN is used in pregnant adult women, from week 24 to week 33 of the pregnancy.

Atosiban SUN works by making the contractions in your womb (uterus) weaker. It also makes the contractions happen less often. It does this by blocking the effect of a natural hormone in your body called “oxytocin” which causes your womb (uterus) to contract.

2. What you need to know before you are given Atosiban SUN

Do not use Atosiban SUN
- If you are allergic to atosiban or any of the other ingredients of this medicine (listed in section 6).
- If you are less than 24 weeks pregnant.
- If you are more than 33 weeks pregnant.
- If your waters have broken (premature rupture of your membranes) and you have completed 30 weeks of your pregnancy or more.
- If your unborn baby (foetus) has an abnormal heart rate.
- If you have bleeding from your vagina and your doctor wants your unborn baby to be delivered straight away.
- If you have something called “severe pre-eclampsia” and your doctor wants your unborn baby to be delivered straight away. Severe pre-eclampsia is when you have very high blood pressure, fluid retention and/or protein in your urine.
- If you have something called “eclampsia” which is similar to “severe pre-eclampsia” but you would also have fits (convulsions). This will mean your unborn baby needs to be delivered straight away.
- If your unborn baby has died.

- If you have or could have an infection of your womb (uterus).
- If your placenta is covering the birth canal.
- If your placenta is detaching from the wall of your womb.
- If you or your unborn baby have any other conditions where it would be dangerous to continue with your pregnancy.

Do not use Atosiban SUN if any of the above apply to you. If you are not sure, talk to your doctor, midwife or pharmacist before you are given Atosiban SUN.

Warnings and precautions
Talk to your doctor, midwife or pharmacist before you are given Atosiban SUN
- If you think your waters might have broken (premature rupture of your membranes).
- If you have kidney or liver problems.
- If you are between 24 and 27 weeks pregnant.
- If you are pregnant with more than one baby.
- If your contractions start again, treatment with Atosiban SUN can be repeated up to three more times.
- If your unborn baby is small for the time of your pregnancy.
- Your womb may be less able to contract after your baby has been born. This may cause bleeding.
- If you are pregnant with more than one baby and/or are given medicines that can delay the birth of your baby, such as medicines used for high blood pressure. This may increase the risk of lung oedema (accumulation of fluid in the lungs).

If any of the above apply to you (or you are not sure), talk to your doctor, midwife or pharmacist before you are given Atosiban SUN.

Children and adolescents
Atosiban SUN has not been studied in pregnant women less than 18 years old.

Other medicines and Atosiban SUN
Tell your doctor, midwife or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding
If you are pregnant and breast-feeding an earlier child, you should stop breast-feeding while you are given Atosiban SUN.

3. How Atosiban SUN will be given

Atosiban SUN will be given to you in a hospital by a doctor, nurse or midwife. They will decide how much you need. They will also make sure the solution is clear and free from particles.

Atosiban SUN will be given into a vein (intravenously) in three stages:
- The first injection of 6.75 mg in 0.9 ml will be slowly injected into your vein over one minute.
- Then a continuous infusion (drip) will be given at a dose of 18 mg per hour for 3 hours.
- Then another continuous infusion (drip) at a dose of 6 mg per hour will be given for up to 45 hours, or until your contractions have stopped.

Treatment should last no longer than 48 hours in total.

Further treatment with Atosiban SUN can be used if your contractions start again. Treatment with Atosiban SUN can be repeated up to three more times.

During treatment with Atosiban SUN, your contractions and your unborn baby’s heart rate may be

monitored.

It is recommended that no more than three re-treatments should be used during a pregnancy.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects seen in the mother are generally mild. There are no known side effects on the unborn or new-born baby.

The following side effects may happen with this medicine:

Very common (may affect more than 1 in 10 people)
- Feeling sick (nausea).

Common (may affect less than 1 in 10 people)
- Headache.
- Feeling dizzy.
- Hot flushes.
- Being sick (vomiting).
- Fast heart beat.
- Low blood pressure. Signs may include feeling dizzy or light-headed.
- A reaction at the site where the injection was given.
- High blood sugar.

Uncommon (may affect less than 1 in 100 people)
- High temperature (fever).
- Difficulty sleeping (insomnia).
- Itching.
- Rash.

Rare (may affect less than 1 in 1,000 people)
- Your womb may be less able to contract after your baby has been born. This may cause bleeding.
- Allergic reactions.

You may experience shortness of breath or lung oedema (accumulation of fluid in the lungs), particularly if you are pregnant with more than one baby and/or are given medicines that can delay the birth of your baby, such as medicines used for high blood pressure.

Reporting of side effects
If you get any side effects, talk to your doctor, midwife or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Atosiban SUN

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP {MM/YYYY}. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C). Dilutions for intravenous administration must be used within 24 hours after preparation.

Store in the original package in order to protect from light.

Do not use Atosiban SUN if you notice particulate matter and discoloration prior to administration.

Do not throw away any medicines in wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Atosiban SUN contains
- The active substance is atosiban.
- Each vial of Atosiban SUN 37.5 mg/5 ml concentrate for solution for infusion contains atosiban acetate equivalent to 37.5 mg of atosiban in 5 ml.
- The other ingredients are mannitol, hydrochloric acid 1M and water for injections.

What Atosiban SUN looks like and contents of the pack
Atosiban SUN 37.5 mg/5 ml concentrate for solution for infusion is a clear, colourless solution without particles.
One pack contains one vial containing 5 ml solution.

Marketing Authorisation Holder and Manufacturer
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For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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This leaflet was last revised in October 2020

Other sources of information
Detailed information on this medicine is available on the European Medicines Agency website: http://www.ema.europa.eu.

INSTRUCTION FOR THE HEALTHCARE PROFESSIONAL

The following information is intended for healthcare professionals only:
(See also section 3)

Instructions for use
Before using Atosiban SUN, the solution should be examined to ensure it is clear and free from particles.

Atosiban SUN is given intravenously in three successive stages:
- The initial intravenous injection of 6.75 mg in 0.9 ml is slowly injected into a vein over one minute.
- A continuous infusion at a rate of 24 ml/hour is given for 3 hours.
- A continuous infusion at a rate of 8 ml/hour is given for up to 45 hours, or until the contractions of the uterus have subsided.

The total duration of the treatment should be no more than 48 hours. Further treatment cycles of Atosiban SUN can be used should contractions recur. It is recommended that no more than three retreatments should be used during a pregnancy.

Preparation of the intravenous infusion
The intravenous infusion is prepared by diluting Atosiban SUN 37.5 mg/5 ml, concentrate for solution for infusion in sodium chloride 9 mg/ml (0.9%) solution for injection, Ringer's lactate solution or 5% w/v glucose solution. This is done by removing 10 ml of solution from a 100 ml infusion bag and replacing it with 10 ml Atosiban SUN 37.5 mg/5 ml concentrate for solution for infusion from two 5 ml vials to obtain a concentration of 75 mg atosiban in 100 ml. If an infusion bag with a different volume is used, a proportional calculation should be made for the preparation.
Atosiban SUN should not be mixed with other medicinal products in the infusion bag.