PACKAGE LEAFLET: INFORMATION FOR THE USER

Atosiban 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 IS AND WHAT IT IS USED FOR

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

Atosiban works by making the contractions in your womb (uterus) less strong. 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

Do not use Atosiban
- 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
- if you are allergic to atosiban or any of the other ingredients of this medicine (listed in section 6).

Do not use Atosiban 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.

Warnings and precautions
Talk to your doctor, midwife or pharmacist before you are given Atosiban
- 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 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.

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

Other medicines and Atosiban
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.

3. HOW ATOSIBAN WILL BE GIVEN

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

During treatment with Atosiban, 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 of a mild severity. There are no known side effects on the unborn or new-born baby.

The following side effects may happen with this medicine.

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

Common (affects less than 1 in 10 people)
- Headache
- Feeling dizzy
- Hot flushes
- Being sick (vomiting)
- Fast heartbeat
- 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 (affects less than 1 in 100 people)
- High temperature (fever)
- Difficulty sleeping (insomnia)
- Itching
- Rash.

Rare (affects 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

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. The expiry date refers to the last day of that month. Once the vial has been opened, the product must be used immediately.

Store in a refrigerator (2°C - 8°C).
Store in the original package in order to protect from light.
Solution after dilution: Chemical and physical in-use stability has been demonstrated for 24 hours at 25 ºC.
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 ºC, unless reconstitution/dilution (etc) has taken place in controlled and validated aseptic conditions.

Do not use this medicine if you notice particulate matter and discoloration prior to administration.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Atosiban contains
The active substance is atosiban.
Each vial (5 ml) of Atosiban 37.5 mg/5 ml concentrate for solution for infusion contains 37.5 mg of atosiban (as acetate).
Each ml of solution contains 7.5 mg atosiban.

The other ingredients are mannitol, hydrochloric acid concentrated and water for injections.

What Atosiban looks like and contents of the pack
Atosiban 37.5 mg/5 ml concentrate for solution for infusion (sterile concentrate) is a clear, colourless solution without particles.

One pack contains one vial containing 5 ml solution. Colourless glass vial, clear, Type I, sealed with grey bromo-butyl rubber stopper type I, and blue flip-off cap.

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This leaflet was last revised in 06/2020

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

Instructions for use
Before using Atosiban, the solution should be examined to ensure it is clear and free from particles.
Atosiban 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 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 solution
The intravenous infusion is prepared by diluting Atosiban 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 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 should not be mixed with other medicinal products in the infusion bag.

Solution after dilution: Chemical and physical in-use stability has been demonstrated for 24 hours at 25 ºC. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 ºC, unless reconstitution/dilution (etc) has taken place in controlled and validated aseptic conditions.