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 start taking 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
- If you get any side effects, talk to your doctor. 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 USE 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 or pharmacist or nurse before using 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 or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy, breast-feeding and fertility
You should only be given this medicine if you are between 24 and 33 weeks of pregnancy. If this does not apply to you, please speak to your doctor. If you are still breast feeding a child from an earlier pregnancy, you should stop during your treatment with Atosiban, as breastfeeding may stimulate uterine contractions.

3. HOW TO USE ATOSIBAN

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 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 (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, pharmacist or nurse. 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. 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. 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.

Dilutions for intravenous administration must be used within 24 hours after preparation.

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 atosiban (as acetate).
Each ml of solution contains 7.5 mg atosiban.

The other ingredients are mannitol, hydrochloric acid 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 12/2019.

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

The vials should be inspected visually for particulate matter and discoloration prior to administration

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, following initial bolus injection of Atosiban 6.75 mg/0.9 ml solution for injection

For intravenous infusion, following the bolus dose, Atosiban 37.5 mg/5 ml concentrate for solution for infusion should be diluted in one of the following solutions:

− sodium chloride 9 mg/ml (0.9%) solution for injection
− Ringer's lactate solution
− 5% w/v glucose solution.

Withdraw 10 ml solution from a 100 ml infusion bag and discard. Replace it by 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.

The reconstituted product is a clear, colourless solution without particles.

The loading infusion is given by infusing 24 ml/hour (i.e. 18 mg/h) of the above prepared solution over the 3 hour period under adequate medical supervision in an obstetric unit. After three hours the infusion rate is reduced to 8 ml/hour.

Prepare new 100 ml bags in the same way as described to allow the infusion to be continued.

If an infusion bag with a different volume is used, a proportional calculation should be made for the preparation.

To achieve accurate dosing, a controlled infusion device is recommended to adjust the rate of flow in drops/min. An intravenous microdrip chamber can provide a convenient range of infusion rates within the recommended dose levels for Atosiban.

If other medicinal products need to be given intravenously at the same time, the intravenous cannula can be shared or another site of intravenous administration can be used. This permits the continued independent control of the rate of infusion.