

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, or pharmacist or nurse.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

1. What Atosiban injection is and what it is used for
2. What you need to know before you take Atosiban injection
3. How Atosiban injection will be given
4. Possible side effects
5. How to store Atosiban injection
6. Contents of the pack and other information

**1. What Atosiban injection is and what it is used for**

The name of your medicine is '**Atosiban 37.5mg/5ml concentrate for solution for infusion**' but in the rest of the leaflet it will be called '**Atosiban injection**'.

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

Atosiban injection 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 take Atosiban injection**

**Do not use Atosiban injection:**

- 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)

**Warnings and precautions**

Talk to your doctor, or pharmacist or nurse before using Atosiban injection

- 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 injection 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 injection

**Children and adolescents**

Atosiban injection has not been studied in pregnant women less than 18 years old.

**Other medicines and Atosiban injection**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

**Pregnancy, breast-feeding and fertility**

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

**3. How Atosiban injection will be given**

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

During treatment with Atosiban injection, 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.



**INSTRUCTION FOR THE HEALTHCARE PROFESSIONAL**

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

**Instructions for use**

Before using Atosiban injection, the solution should be examined to ensure it is clear and free from particles.

Atosiban injection 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 injection can be used should contractions recur. It is recommended that no more than three retreatments should be used during a pregnancy.