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 is it used for
2. Before you are given 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

What Atosiban injection is and what is it used for

The name of your medicine is 'Atosiban 37.5 mg/5 ml 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 (fetus) has an abnormal total.
- If your unborn baby is small for the time of your pregnancy.
- If you have kidney or liver problems.
- If you think your waters might have broken (premature rupture of your membranes).
- If you have severe pre-eclampsia but you would also have fits (convulsions). This will mean your womb (uterus) has an abnormal heart rate.
- If you have had a reaction at the site where the injection was given.
- If you have or could have an infection of your womb.
- 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 some medicines might have broken your membranes.
- 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.
- If your heart rate is at a low rate.
- If you have kidney or liver problems.

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 avoid breast-feeding while you are given Atosiban injection.

How Atosiban injection will be given

Atosiban injection will be given to you in a hospital by a doctor, a nurse or a midwife. They will decide how much of this medicine you need. You may need more than one injection.

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:

- High temperature (fever).
- Low blood pressure. Signs may include feeling dizzy or light-headed.
- Feeling dizzy.
- Feeling sick (nausea).
- Diarrhoea.
- Headache.

The side effects seen in the unborn baby are generally:

- A reaction at the site where the injection was given.
- If your child has been born. This may cause bleeding.
- Allergic reactions
- Anaphylaxis (a severe allergic reaction). If you or your child have had an allergic reaction to atosiban or any of the other ingredients of this medicine, you should not be given atosiban.

The side effects seen in the mother and/or the unborn baby may include:

- If more than three re-treatments should be used during a pregnancy.

4. Possible side effects
The following side effects may happen with this medicine:

**Very common** (affects more than 1 in 10 people)
- Headache
- Asthma
- Itching
- Rash

**Common** (affects less than 1 in 10 people)
- Asthma
- Itching
- Rash

**Uncommon** (affects less than 1 in 100 people)
- High temperature (fever)
- Difficulty sleeping (insomnia)
- Itching

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 (see contact details below). By reporting side effects you can help provide more information on the safety of this medicine.

**United Kingdom**

Yellow Card Scheme
Website: "http://www.mhra.gov.uk/yellowcard" or search for MHRA Yellow Card in the Google Play or Apple App Store

**Ireland**

HPRA Pharmacovigilance
Eastlink Terrace
PIL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafe@hpra.ie

**Malta**

ADR Reporting
Website: www.medicinesauthority.mt/medportal

**6. How to store Atosiban injection**

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.

Store in a refrigerator (2°C - 8°C).

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

Chemical and physical stability of the diluted product has been demonstrated for a period of 72 hours at 23-27°C.

From a microbiological point of view, unless the product has been demonstrated for a period of 72 hours at 23-27°C.

**Preparation of the intravenous infusion**

The intravenous infusion is prepared by diluting Atosiban 37.5 mg/ml concentrate for solution for injection in sodium chloride 0.9% (0.9%) solution for injection, Ringer’s lactate solution or 5% w/v glucose solution. This is done by removing 10 ml from a 200 ml infusion bag and replacing it with 10 Atosiban 37.5 mg/ml concentrate for solution for injection 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 immediately, i.e. cause storage times and conditions are the responsibility of the user.

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

**What Atosiban injection contains**

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

**What Atosiban injection looks like and contents of the pack**

Atosiban 37.5 mg/ml concentrate for solution for infusion is a clear, colourless solution without particles. One pack contains one vial containing 5 ml solution.

**Packaging and storage**

Atosiban injection should be stored at 2-8°C in the original pack.

**Marketing Authorisation Holder and Manufacturer:**

**Marketing Authorisation Holder**

United Kingdom
Accord Healthcare Limited
Sage House, 319 Pinner Road
North Harrow, Middlesex, HA1 4HF

**Manufacturer**

Accord Healthcare Ireland Limited
Euro House
Euro Business Park
Little Island
Cork T54 K857
Ireland

Accord Healthcare Polska Sp z o.o., ul. Lutomierska 50,95-200 Pabianice, Poland

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