Abortion is one of the most common reasons for which Atosiban is used. It is a medication that delays the birth of your baby so that you can have time to decide what you want to do. Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

1. What Atosiban is and what it is used for

Atosiban contains atosiban. Atosiban can be used to delay the premature birth of your baby. It is usually given to pregnant women in the second half of pregnancy, from week 24 to week 37 of the pregnancy.

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

2. What you need to know before you start using this medicine

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 more than 24 hours ago. If any of the above apply to you (or you are not sure), talk to your doctor, midwife or pharmacist.

If you are pregnant with more than one baby, you should talk to your doctor, midwife or pharmacist before you are given Atosiban.

A reaction at the site where the injection was given may be monitored. Further treatment with Atosiban can be used should there be no improvement.

3. How Atosiban will be given

Atosiban is given in 3 successive stages:

- A continuous infusion at a rate of 8 ml/hour for 6 hours in total.
- Then another continuous infusion (drip) at a dose of 18 mg per hour for 3 hours.
- A third continuous infusion at a dose of 5 mg per hour will be given 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 only if you have had contractions in stage 1 treatment. 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 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 baby or any of the other ingredients of this medicine (listed in section 6).

The following side effects may happen with this medicine:

Common (may affect more than 1 in 10 people):
- Feeling dizzy

Common (may affect less than 1 in 10 people):
- Feeling hot
- Being sick (vomiting)
- Headache
- Low blood pressure.
- Being sick (vomiting)

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

Rare side effects (may affect less than 1 in 10,000 people):
- Your womb may be less able to contract after Atosiban has been used.
- You are pregnant with more than one baby and/or you have given medicines that can delay the birth of your baby, such as misoprostol used for high blood pressure. This may increase the risk of long bleeding (which is more likely to happen in the third stage).

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 mother/mother for is given for up to 48 hours.

Other medicines and Atosiban

Talk to your doctor, pharmacist or midwife before you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

If you are pregnant and breast-feeding an elderly child, you should avoid breast-feeding while you are given Atosiban.

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Like all medicines, this medicine can cause side effects, although not everybody gets them.

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- Feeling dizzy (nausea)

Common (may affect less than 1 in 10 people):
- Feeling hot
- Being sick (vomiting)
- Headache
- Low blood pressure.
- Being sick (vomiting)

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- High temperature (fever)
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Other medicines and Atosiban

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Pregnancy and breast-feeding

If you are pregnant and breast-feeding an elderly child, you should avoid breast-feeding while you are given Atosiban.
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 medications that cause bleeding.

6. Contents of the pack and other information

What Atosiban contains
- The active substance is atosiban.
- Each pre-filled syringe of Atosiban 6.75 mg Solution for injection contains atosiban equivalent to 6.75 mg of atosiban in 0.9 ml.
- The other ingredients are mannitol, acetate equivalent to 6.75 mg of atosiban in 0.9 ml.
- The other ingredients are mannitol, hydrochloric acid and water for injection.

What Atosiban looks like and contents of the pack
Atosiban 6.75 mg Solution for injection is a clear, colourless solution without particles. One pack contains one pre-filled syringe containing 6.9 ml solution.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Unipharma
Accord Healthcare Limited
Sage House, 313 Prinner Road, Harrow, HA1 4HF
United Kingdom

Ireland
Accord Healthcare Ireland Limited
Euro House
Eurol Business Park
Little Island
Co. Cork, T81 K601
Ireland

Manufacturers
- Accord Healthcare Limited
- Accord Healthcare Limited
- Accord Healthcare Polska Sp.o.o.

Language
English

This medicinal product is authorised in the Member States of the EEA under the following names:

Name of the medicinal product
Austria
Atosiban
6,75 mg/6 ml injektionslösning i en är

Germany
Atosiban
6,75 mg/6 ml injektionslösning i en är

Denmark
Atosiban
6,75 mg/6 ml

Finland
Atosiban
6,75 mg/6 ml

Italy
Atosiban
6,75 mg/6 ml

Lithuania
Atosiban
6,75 mg/6 ml injektionsų solva

Malta
Atosiban 6,75 mg Solution for injection in pre-filled syringe

Bulgaria
Atosiban
6,75 mg/6 ml

Portugal
Atosiban
6,75 mg/6 ml

Sweden
Atosiban
6,75 mg/6 ml

This leaflet was last revised in 10/2018.

The total duration of the treatment should be no more than 48 hours. Further treatment cycles of Atosiban should be avoided. In rare cases, it recommended that no more than three re-treatments should be used during a pregnancy.