

Tractocile®

7.5 mg/ml solution for injection
atosiban

PACKAGE LEAFLET

Read all of this leaflet carefully before you start using this medicine

- This leaflet contains practical information on **Tractocile®**.
- Keep this leaflet. You may need to read it again. Should you have any questions or if you are not sure about anything, please ask your doctor or your pharmacist.
- **Tractocile®** is a medicinal product to be used in hospital and should only be administered under supervision of experienced hospital personnel.

In this leaflet:

1. What **Tractocile®** is and what it is used for
2. Before you use **Tractocile®**
3. How to use **Tractocile®**
4. Possible side effects
5. Storing **Tractocile®**

Tractocile® 7.5 mg/ml, solution for injection
atosiban

The active substance is atosiban.
The other ingredients are mannitol, hydrochloric acid and water for injections.

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1. WHAT TRACTOCILE® IS AND WHAT IT IS USED FOR

Each vial of **Tractocile®** 7.5 mg/ml, solution for injection, contains atosiban acetate equivalent to 6.75 mg of atosiban in 0.9 ml.

Atosiban blocks the ability of the natural hormone oxytocin to cause the uterus (womb) to contract. **Tractocile®** can be used to decrease the frequency and intensity of uterine contractions in pregnant women in order to delay a premature birth.

2. BEFORE YOU USE TRACTOCILE®

Do not use **Tractocile®**:

- if your pregnancy is less than 24 weeks or more than 33 weeks
- if you have premature rupture of the membranes after 30 weeks of pregnancy
- if the foetus is growing insufficiently and has an abnormal foetal heart rate
- if you experience uterine bleeding that requires immediate delivery
- if you have severe pre-eclampsia (high blood pressure, fluid retention and/or protein in the urine) or eclampsia (convulsions associated with pre-eclampsia) requiring delivery
- if the foetus has died
- if you have a suspected infection of the uterus
- if the placenta is covering the birth canal
- if the placenta is detaching
- if you or the foetus have conditions in which continuation of pregnancy are regarded undesirable or hazardous
- if you are allergic to atosiban or any of the other ingredients of **Tractocile®**

Take special care with **Tractocile®**:

- if premature rupture of your membranes cannot be excluded
- if you have kidney or liver problems
- if the placenta is not in a normal position
- if you have a multiple pregnancy or a pregnancy between 24 and 27 weeks
- if contractions recur, treatment with **Tractocile®** can be repeated up to three more times
- if the foetus is small for the time of pregnancy
- during treatment with **Tractocile®**, your contractions and the foetal heart rate may be monitored
- after your baby has been delivered, **Tractocile®** may theoretically reduce the ability of the uterus to contract. This may cause bleeding.

Using other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

3. HOW TO USE TRACTOCILE®

Tractocile® is a medicine that is used only in hospital and should only be administered by qualified staff.

Before using **Tractocile®**, the solution should be examined to ensure it is clear and free from particles.

Tractocile® is given intravenously in three successive stages:

- The initial intravenous injection of 6.75mg in 0.9ml is slowly injected into a vein over one minute.
- A continuous infusion at a dose of 18mg/hour is given for 3 hours.
- A continuous infusion at a dose of 6mg/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 **Tractocile®** 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

The intravenous infusion is prepared by diluting **Tractocile®** 7.5mg/ml, concentrate for solution for infusion in 0.9% w/v sodium chloride solution, Ringer's lactate solution or 5% w/v glucose solution. This is done by removing 10ml of solution from a 100ml infusion bag and replacing it with 10ml **Tractocile®** 7.5mg/ml concentrate for solution for infusion from two 5ml vials to obtain a concentration of 75mg atosiban in 100ml. If an infusion bag with a different volume is used, a proportional calculation should be made for the preparation.

Tractocile® should not be mixed with other medicinal products in the infusion bag.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **Tractocile®** can have side effects. The observed side effects for the mother were generally of a mild severity. There are no known side effects on the foetus or newborn baby.

For the mother the most commonly reported side effects are nausea, headache, dizziness, hot flushes, vomiting, rapid heart beat, low blood pressure, injection site reaction and high blood sugar.

Uncommon side effects include fever, insomnia, itching and rash. Rare side effects include a reduction in the ability of the uterus to contract after your baby has been delivered, which may cause bleeding. Allergic reaction has been rarely reported.

If you notice these or any other side effects not mentioned in this leaflet, please inform your doctor, midwife or pharmacist.

5. STORING TRACTOCILE®

Keep out of the reach and sight of children.

Store at 2°C - 8°C (in a refrigerator).
Store in the original container.

Do not use after the expiry date stated on the label.

Do not use **Tractocile®** if you notice particulate matter and discoloration prior to administration.

Once the vial has been opened, the product must be used immediately.

This leaflet was last approved on 20 January 2000.

Further information

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

THIS IS A MEDICINE

- A MEDICINE IS A PRODUCT WHICH AFFECTS YOUR HEALTH, AND ITS CONSUMPTION CONTRARY TO INSTRUCTIONS IS DANGEROUS FOR YOU.
- STRICTLY FOLLOW THE DOCTOR'S PRESCRIPTION, THE METHOD OF USE AND THE INSTRUCTIONS OF THE PHARMACIST WHO SOLD THE MEDICINE.
- THE DOCTOR AND THE PHARMACIST ARE EXPERTS IN MEDICINE, ITS BENEFITS AND RISKS.
- DO NOT BY YOURSELF INTERRUPT THE PERIOD OR TREATMENT PRESCRIBED FOR YOU.
- DO NOT REPEAT THE SAME PRESCRIPTION WITHOUT CONSULTING YOUR DOCTOR.

Council of Arab Health Ministers
Union of Arab Pharmacists