PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

Tractocile® Solution for injection 7,5 mg/ml (6,75 mg/0,9 ml)

Tractocile® Concentrate for solution for infusion 7,5 mg/ml (37,5 mg/5 ml)

Atosiban.

Tractocile® contains sugar.

Tractocile® Solution for injection: Contains mannitol 45 mg per vial.

Tractocile® Concentrate for solution for infusion: Contains mannitol 250 mg per vial.

Read all of this leaflet carefully before you are given Tractocile®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What **Tractocile®** is and what it is used for

2. What you need to know before you use **Tractocile®**

3. How to use **Tractocile®**

4. Possible side effects

5. How to store **Tractocile®**

6. Contents of the pack and other information

1. What Tractocile® is and what it is used for

Tractocile® contains atosiban. **Tractocile®** can be used to delay the premature birth of your baby. **Tractocile®** is used in pregnant adult women, from week 26 to week 33 of the pregnancy.

Tractocile® 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 Tractocile®

Tractocile® should not be administered to you:

- if you are less than 26 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 hypersensitive (allergic) to atosiban or to any other ingredients of **Tractocile®** (listed in section 6).

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection/infusion:

Special care should be taken with **Tractocile®**:

- if you think your waters might have broken (premature rupture of your membranes).
- if you have kidney or liver problems.
- if you are pregnant with more than one baby.
- if your contractions start again, treatment with **Tractocile®** 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).

Children and adolescents

Tractocile® has not been studied in pregnant women less than 18 years old.

Other medicines and Tractocile®

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Pregnancy, breastfeeding and fertility

If you are pregnant and breastfeeding an earlier child, you should stop breastfeeding while you are given **Tractocile®**.

Driving and using machines

Atosiban may cause dizziness. If you experience dizziness, you should not drive or use machines.

3. How Tractocile® will be given to you

Do not share medicines prescribed for you with any other person.

Your doctor will tell you how long your treatment with **Tractocile®** will last. If you have the impression that the

effect of **Tractocile®** is too strong or too weak, tell your doctor or pharmacist.

You will not be expected to give yourself **Tractocile®**. It will be given to you by a person who is qualified to do so. They will make sure the solution is clear and free from particles.

Tractocile® 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 **Tractocile®** can be used if your contractions start again. Treatment with **Tractocile®** can be repeated up to three more times.

During treatment with **Tractocile®**, 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.

If you use more Tractocile® than you should

Since a healthcare provider will administer **Tractocile®**, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use Tractocile®

Since a healthcare provider will administer **Tractocile®**, it is unlikely that the dose will be missed.

4. Possible side effects

Tractocile® can have side effects.

Not all side effects reported for **Tractocile®** are included in this leaflet. Should your general health worsen or if you

experience any untoward effects while receiving **Tractocile®**, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop receiving **Tractocile®** and tell your doctor immediately:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching

These are all very serious side effects. If you have them, you may have had a serious reaction to **Tractocile®**. You may need urgent medical attention.

Tell your doctor immediately if you notice any of the following:

Frequent side effects:

- feeling sick (nausea)
- headache
- feeling dizzy
- hot flushes
- being sick (vomiting)
- fast heartbeat
- Low blood pressure. Signs may include feeling dizzy or light-headed.
- A reaction at the site where the injection was given.
- high blood sugar

Less frequent

- high temperature (fever)
- difficulty sleeping (insomnia)
- itching
- rash

- your womb may be less able to contract after your baby has been born. This may cause bleeding

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **Tractocile®.**

5. How to store Tractocile®

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

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.

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

6. Contents of the pack and other information

What Tractocile® contains

The active substance is atosiban.

Each vial of **Tractocile® Solution for injection** contains atosiban acetate equivalent to 6,75 mg of atosiban in 0,9 ml.

Each vial of **Tractocile® Concentrate for solution for infusion** contains atosiban acetate equivalent to 37,5 mg of atosiban in 5 ml.

The other ingredients are mannitol, hydrochloric acid and water for injections.

What Tractocile® looks like and contents of the pack

Tractocile® Solution for injection is a clear, colourless solution without particles.

2 ml clear, colourless glass vials containing 0,9 ml solution, sealed with grey rubber stopper, and flip-off cap of polypropylene and aluminium.

One pack contains one vial containing 0,9 ml solution.

Tractocile® Concentrate for solution for infusion is a clear, colourless solution without particles.

5 ml clear, colourless glass vials, sealed with grey rubber stopper, type I, and flip-off cap of polypropylene and aluminium.

One pack contains one vial containing 5 ml solution.

Holder of Certificate of Registration

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Tractocile® Concentrate for solution for infusion: A36/18.9/0336

Tractocile® Solution for injection:

Namibia S2 Reg No/Nr: 10/18.9/0425

Botswana S2 Reg No/Nr: BOT1302385

Tractocile® Concentrate for solution for infusion:

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