European Medicines Agency

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Tractocile
atosiban

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis for the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Tractocile?
Tractocile is a solution for injection, and a concentrate that is made up into a solution for infusion (drip into a vein). Both contain the active substance atosiban (7.5 mg per millilitre).

What is Tractocile used for?
Tractocile is used to delay birth in adult women who are 24 to 33 weeks pregnant, when they show signs that they may give birth pre-term (prematurely). These signs include:
- regular contractions lasting at least 30 seconds at a rate of at least four every 30 minutes;
- dilation of the cervix (the neck of the womb) of 1 to 3 cm and an effacement (a measure of the thinness of the cervix) of 50% or more.

In addition, the baby must have a normal heart rate.
The medicine can only be obtained with a prescription.

How is Tractocile used?
Treatment with Tractocile should be carried out by a doctor who has experience in the treatment of pre-term labour.
Treatment should be started as soon as possible after diagnosis of pre-term labour. Tractocile is given into a vein in three stages, over a maximum of 48 hours: an initial injection into a vein (6.75 mg), followed by a high-dose infusion (18 mg per hour) over three hours, then a lower dose infusion (6 mg per hour) lasting up to 45 hours. If contractions come back, treatment with Tractocile can be repeated up to three more times during the pregnancy.

How does Tractocile work?
The active substance in Tractocile, atosiban, is an antagonist of the natural hormone oxytocin. This means that atosiban blocks the action of oxytocin. Oxytocin is the hormone involved in starting contractions of the womb. By blocking the action of oxytocin, Tractocile prevents contractions and causes the womb to relax, helping to delay birth.

How has Tractocile been studied?
The ability of Tractocile to delay pre-term birth was studied in 742 women who were 23 to 33 weeks pregnant in three main studies. Tractocile was compared with ritodine, terbutaline and salbutamol (all

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from a different class of medicines used in pre-term labour called beta-agonists). The main measure of effectiveness was whether the treatment had worked after a week.

What benefit has Tractocile shown during the studies?
Looking at the results of the three main studies together, 60% of the women treated with Tractocile were still pregnant one week after treatment (201 out of 337) compared with 48% of the women treated with the comparator medicines (163 out of 342). There were too few women with a pregnancy at less than 28 weeks for the effectiveness of Tractocile in comparison to beta-agonists to be established in this group. The better result with Tractocile over the beta-agonists might have been because it caused fewer side effects, thereby allowing the patients to receive a full course of treatment.

What is the risk associated with Tractocile?
The most common side effect with Tractocile (seen in more than 1 patient in 10) is nausea (feeling sick). No side effects have been noted in the newborn baby. For the full list of all side effects reported with Tractocile, see the Package Leaflet.
Tractocile should not be used in people who may be hypersensitive (allergic) to atosiban or any of the other ingredients. It must not be used in women whose pregnancy is less than 24 weeks or more than 33 weeks, in women who have premature rupture of the membranes (when the waters break early) after 30 weeks of pregnancy, bleeding from the womb, eclampsia (a dangerous condition at the end of pregnancy caused by toxins in the blood), pre-eclampsia (a condition that can lead to eclampsia) or problems with the baby or placenta, or when continuing the pregnancy could be dangerous for the mother or baby. For the full list of restrictions, see the Package Leaflet.

Why has Tractocile been approved?
The Committee for Medicinal Products for Human Use (CHMP) concluded that Tractocile has shown an effectiveness in delaying pre-term birth that is the same as seen with beta-agonists, and that the better outcome with Tractocile was due to the medicine being better tolerated. The Committee decided that Tractocile's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Tractocile:
The European Commission granted a marketing authorisation valid throughout the European Union for Tractocile on 20 January 2000. The marketing authorisation holder is Ferring Pharmaceuticals A/S. The marketing authorisation is valid for an unlimited period.

The full EPAR for Tractocile is available here.

This summary was last updated in 12-2009.