Prescribing Information: Tractocile® 7.5mg/ml solution for injection and Tractocile® 7.5mg/ml concentrate for solution for infusion.

Please consult the full Summary of Product Characteristics before prescribing. Name of Product: Tractocile® 7.5mg/ml solution for injection. Tractocile® 7.5mg/ml concentrate for solution for infusion. **Composition:** Tractocile® 7.5mg/ml solution for injection contains 6.75mg atosiban/0.9ml solution. Tractocile® 7.5mg/ml concentrate for solution for infusion contains 37.5mg atosiban/5ml concentrate for solution. **Indication:** Delay imminent preterm birth in pregnant women with: regular uterine contractions of at least 30 seconds duration at a rate of ≥ 4 per 30 minutes; cervical dilation of 1 to 3cm (0-3 for nulliparas) and effacement of ≥ 50%; gestational age from 24 until 33 completed weeks; normal fetal heart rate. **Dosage:** Tractocile® is administered intravenously in 3 successive stages: initial bolus dose (6.75mg), using Tractocile® 7.5mg/ml solution for injection, immediately followed by a continuous infusion of Tractocile® 7.5mg/ml concentrate for solution for infusion: An initial infusion rate of 300 micrograms/min is used for 3 hours followed by a lower dose of 100 micrograms/min for up to 45 hours. The duration of the treatment should not exceed 48 hours. The total dose given during a full course of Tractocile® therapy should not exceed 330.75 mg of atosiban. Intravenous therapy using the initial bolus injection should be started as soon as possible after diagnosis of preterm labour. If uterine contractions persist during treatment with Tractocile®, alternative therapy should be considered. If re-treatment with Tractocile® is needed, it should follow the same treatment schedule. **Contraindications:** Tractocile® should not be used in the following conditions: gestational age below 24 or over 33 completed weeks; premature rupture of the membranes >30 weeks of gestation; abnormal fetal heart rate; antepartum uterine haemorrhage requiring immediate delivery; eclampsia and severe preeclampsia requiring delivery; intrauterine fetal death; suspected intrauterine infection; placenta previa; abruptio placenta; any other conditions of the mother or fetus in which which continuation of pregnancy is hazardous; known hypersensitivity to atosiban or any of the excipients. **Special Warnings and Precautions:** In patients with premature rupture of membranes, the benefits of delaying delivery should be balanced against the potential risk of chorioamnionitis. No experience in patients with impaired liver or kidney function or with an abnormal placental site. Limited experience in multiple pregnancies or gestational age group between 24 and 27 weeks. Multiple pregnancy and tocolytics like calcium channel blockers and beta-mimetics are known to be associated with increased risk of respiratory events like dyspnoea and pulmonary oedema; Therefore, atosiban should be used with caution in case of multiple pregnancy and/or concomitant administration of other tocolytics. Experience with Tractocile® is limited up to 3 re-treatments. In intrauterine growth retardation, the decision to continue treatment depends on the assessment of fetal maturity -monitoring of uterine contractions and fetal heart rate should be considered during treatment. Tractocile® may theoretically facilitate uterine relaxation and postpartum bleeding, although inadequate uterus contraction postpartum has not been observed. **Side effects:** Very common: nausea. Common: hyperglycaemia, headache, dizziness, hot flush, tachycardia, hypotension, vomiting, injection site reaction. Uncommon: insomnia, pruritis, rash, pyrexia. Isolated case of allergic reactions. **Nature and Contents of Container:** Tractocile® 7.5mg/ml solution for injection: One 0.9ml colourless glass vial contains 0.9 ml solution, corresponding to 6.75 mg atosiban. Tractocile® 7.5mg/ml concentrate for solution for infusion: One 5ml colourless glass vial contains 5 ml solution, corresponding to 37.5 mg atosiban. **Marketing Authorisation Number:** Tractocile® 7.5mg/ml solution for injection: EU/1/99/124/001. Tractocile® 7.5mg/ml concentrate for solution for infusion: EU/1/99/124/002. **Marketing Authorisation Holder:** Ferring Pharmaceuticals A/S, Kay Fiskers Plads 11, 2300 København S, Denmark. **Legal Category:** POM. **Basic NHS Price:** Tractocile® 7.5mg/ml solution for injection: £18.41. Tractocile® 7.5mg/ml concentrate for solution for infusion: £52.82. **Date of Preparation of Prescribing Information:** October 2021.UK-TE-2100001

Adverse events should be reported. Reporting forms and information can be found at **www.mhra.gov.uk/yellowcard.**
Adverse events should also be reported to Ferring Pharmaceuticals Ltd.
Tel: 0800 111 4126. Email: medical.uk@ferring.com