

## Who can administer

Who can administer: May be administered by competent doctor or a nurse/midwife

## Important information

- Atosiban must be initiated and maintained by a physician experienced in the treatment of pre-term labour

## Available preparations

Tractocile 6.75mg in 0.9ml vial

Tractocile 37.5mg in 5ml vial

## Reconstitution

### **Already in solution**

Dilute the 37.5mg per 5ml injection further prior to infusion

## Infusion fluids

Sodium chloride 0.9% or Glucose 5%

## Methods of intravenous administration

### **Bolus intravenous injection (initial dose only)**

- Draw up 0.9ml from vial containing 6.75mg/0.9ml and administer as a bolus injection over one minute, followed by intravenous infusion as outlined below

### **Intermittent intravenous infusion**

- Remove and discard 10ml fluid from 100ml infusion solution
- Add contents of two vials of 37.5mg/5ml (total 75mg in 10ml) to the bag to give a solution of approximately 75mg per 100ml (0.75mg/ml)
- Prepare new 100ml bags in the same way to allow the infusion to be continued

## Dose in adults

### **Initial bolus dose**

- Give 6.75mg (using the 6.75mg/0.9ml vial)
- Followed immediately by an infusion as described below

### **Intravenous infusion**

- Using a solution as outlined above (75mg in 100ml)
- Give 24ml per hour for three hours (equivalent to 18mg per hour)
- Followed by 8ml per hour for up to a further 45 hours (equivalent to 6mg per hour)
- The duration of treatment should not exceed 48 hours (total dose during a full course of treatment)

should not exceed 330.75mg atosiban)

### **Retreatment**

- In case a re-treatment with atosiban is needed, it should also commence with a bolus injection of 6.75mg, followed by an infusion as outlined above
- There is only limited clinical experience available with multiple re-treatments (up to 3 re-treatments)

### **Renal impairment**

- Dosage adjustment is unlikely to be needed

### **Hepatic impairment**

- Use atosiban with caution

## Monitoring

- Monitor uterine contractions and foetal heart rate
- In case of persistence of uterine contractions during treatment with atosiban, alternative treatment should be considered

## Storage

Store between 2 and 8°C

## References

SPC March 2022

## Therapeutic classification

Oxytocin receptor antagonist