OXYTOCIN 5 IU
OXYTOCIN 10 IU

Solution for Injection

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. WHAT OXYTOCIN 5 IU SOLUTION FOR INJECTION OR OXYTOCIN 10 IU SOLUTION FOR INJECTION ARE AND WHAT THEY ARE USED FOR.

Each Oxytocin ampoule contains oxytocin EP, 5 IU (International Units) or 10 IU in 1 ml solution, equivalent to 8.5 micrograms or 17 micrograms respectively. Oxytocin is a drug that belongs to the group of medicines called oxytocins and it is identical with oxytocin, a hormone released by the pituitary gland, which has an effect on the muscles of the uterus (womb). Oxytocin is used to help the muscles of the womb contract.

Oxytocin may be used to induce labour, or to stimulate labour where the contractions are not adequate, or after delivery of the baby where there may be weak or absent contraction of the uterus or to prevent or treat uterine bleeding. It may also be used during caesarean section or as additional therapy for the management of miscarriage.

2. BEFORE YOU TAKE OXYTOCIN 5 IU SOLUTION FOR INJECTION OR OXYTOCIN 10 IU SOLUTION FOR INJECTION

Do not take Oxytocin:

- if you are allergic (hypersensitive) to oxytocin or any of the other ingredients of the solution
- if you have any of the following conditions :
  - dystocia, fragility or overdistension of the uterus,
  - where your healthcare professional considers spontaneous delivery is inadvisable for foetal or maternal reasons, (such as foetal malpresentation, placenta praevia (the placenta is over the cervix), cord presentation, previous classical caesarean section, and other conditions which your healthcare professional will advise you about).

Oxytocin will not be used for a prolonged period if:

- Your contractions do not respond,
- You have severe problems with your heart or circulation,

- You have a condition known as pre-eclamptic toxaemia (high blood pressure, swelling and protein in the urine),
- You have hypertonic uterine contractions or foetal distress, when delivery is not imminent,
- You have predisposition to amniotic fluid embolism (foetal death in utero, retroplacentar hematoma).

Special care with Oxytocin will be taken:
- if you are over 35 years old,
- if you have had a previous caesarean section,
- if you have mild or moderately raised blood pressure or heart problems,
- if normal delivery may be difficult for you due to the small size of your pelvis or the large head of the baby,
- if you are likely to need high doses over a long period of time,
- if you have had an epidural (caudal) anaesthetic block, oxytocin may increase the effects of some drugs used to constrict the blood vessels,
- if you are taking or have taken other medicines:
- prostaglandins in the last 6 hours (the effect may be increased),
- some anaesthetics given by inhalation such as halothane or cyclopropane (they may reduce the effect of oxytocin or may cause heart problems).

Please tell your doctor or midwife if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Important information about some of the ingredients of Oxytocin:
Each ampoule contains 2.9 mg (0.13 mmol) of sodium.

Latex allergy
The active substance in might cause a severe allergic reaction (anaphylaxis) in patients with latex allergy. Please tell your doctor if you know you are allergic to latex.

3. TREATMENT WITH OXYTOCIN

Oxytocin should only be given under medical supervision and in a hospital.
The dose used will vary depending on the reason for its use.
- When being used for induction of labour or to stimulate existing labour, oxytocin will usually be diluted in 500 ml Saline or 5% Dextrose before use and will be given directly into a vein (intravenously) by drip infusion (slowly) or using an infusion pump. The initial infusion rate will be 2 to 8 drops/min; this may be gradually increased to a maximum rate of 40 drops/min. Once your contractions reach an adequate level of about 3-4 contractions per 10 minutes, the infusion rate will often be reduced.
- For caesarean section, 5 IU will slowly be injected into the vein immediately after delivery of your baby.
- For prevention of bleeding after delivery, 5 IU will slowly be injected into your vein after delivery of the placenta.
- For treatment of bleeding after delivery, 5 IU will be slowly injected into your vein, followed, in some cases, by a drip containing 5 to 20 IU oxytocin.
- For miscarriage, 5 IU will be slowly injected into your vein, followed, if necessary by a drip at a high rate (40 to 80 drops/min).

If you receive more Oxytocin than you should or if you miss a dose:
As this medicine will be given to you by a healthcare professional in hospital, it is very unlikely that an overdose or missed dose will happen.
If you have any further questions on the use of this product, ask your doctor or midwife.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Oxytocin can cause side effects, although not everybody gets them.

Rare side effects (more than 1 in 10,000 patients) of Oxytocin include:
- Nausea, vomiting,
- Fast or slow heartbeat,
- A blood clot following the birth of your baby.

Very rarely, if high doses of Oxytocin are given with large volumes of fluids through a drip the condition of water intoxication may occur.

Symptoms may include:
- Headache, nausea, vomiting, seizures,

Exceptionally, side effects of Oxytocin include: skin rashes and anaphylactoid reactions, hypotension, or anaphylactic shock.

If any of the side effects gets worse, or if you notice any side effects not listed in this leaflet, please tell your doctor or midwife.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE OXYTOCIN

The hospital pharmacy will store this medicine in a refrigerator at 2°C to 8°C. It may be stored at 25°C for 6 months, but then discarded.

Keep Oxytocin out of the reach and sight of children.

The pharmacy will not use OXYTOCIN after the expiry date that is stated on the label.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Oxytocin contains:
The active substance is oxytocin.
The other ingredients are sodium chloride, sodium acetate trihydrate, acetic acid, glacial and water for injection.

What Oxytocin looks like and contents of the pack:
Your medicinal product comes in a clear glass 1 ml ampoule. Boxes of 5, 10, 50 or 100 ampoules.

Marketing Authorisation Holder:
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TECHNICAL LEAFLET

Safety information:
For intravenous infusion or intravenous injection.

Incompatibilities:
Oxytocin should not be infused via the same apparatus as blood or plasma, because the peptide linkages are rapidly inactivated by oxytocin-inactivating enzymes. Oxytocin is incompatible with solutions containing sodium metabisulphite as a stabiliser.

Instructions on preparation and dilution:
Snap ampoules: no file required.
Oxytocin is compatible with the following infusion fluids, but due attention should be paid to the advisability of using electrolyte fluids in individual patients: sodium/potassium chloride (103 mmol Na+ and 51 mmol K+), sodium bicarbonate 1.39%, sodium chloride 0.9%, sodium lactate 1.72%, dextrose 5%, laevulose 20%, macrodex 6%, rheomacrodex 10%, Ringer's solution.
For drip infusion it is recommended that 5 IU of oxytocin be added to 500 ml of a physiological electrolyte solution. For patients in whom infusion of sodium chloride must be avoided, 5% dextrose solution may be used as the diluent. To ensure even mixing, the bottle or bag must be turned upside down several times before use.

Administration:
Induction or enhancement of labour: Oxytocin should not be started for 6 hours following administration of vaginal prostaglandins. Oxytocin should be administered as an iv drip infusion or, preferably, by means of a variable-speed infusion pump. For drip infusion it is recommended that 5 IU of oxytocin be added to 500ml of a physiological electrolyte solution. For patients in whom infusion of sodium chloride must be avoided, 5% dextrose solution may be used as the diluent (see Section 4.4 "Special warnings and precautions for use"). To ensure even mixing, the bottle or bag must be turned upside down several times before use.
The initial infusion rate should be set at 1 to 4 mU/min (2 to 8 drops/min). It may be gradually increased at intervals not shorter than 20 min, until a contraction pattern similar to that of normal labour is established. In pregnancy near term this can often be achieved with an infusion of less than 10 mU/min (20 drops/min), and the recommended maximum rate is 20 mU/min (40 drops/min). In the unusual event that higher rates are required, as may occur in the management of foetal death in utero or for induction of labour at an earlier stage of pregnancy, when the uterus is less sensitive to oxytocin, it is advisable to use a more concentrated Oxytocin solution, e.g., 10 IU in 500 ml.
When using a motor-driven infusion pump which delivers smaller volumes than those given by drip infusion, the concentration suitable for infusion within the recommended dosage range must be calculated according to the specifications of the pump.

The frequency, strength, and duration of contractions as well as the foetal heart rate must be carefully monitored throughout the infusion. Once an adequate level of uterine activity is attained, aiming for 3 to 4 contractions every 10 minutes, the infusion rate can often be reduced. In the event of uterine hyperactivity and/or foetal distress, the infusion must be discontinued immediately.

If, in women who are at term or near term, regular contractions are not established after the infusion of a total amount of 5 IU, it is recommended that the attempt to induce labour be ceased; it may be repeated on the following day, starting again from a rate of 1 to 4 mU/min (see Section 4.3 “Contra-indications”).

Caesarean section: 5 IU by slow iv injection immediately after delivery.

Prevention of postpartum uterine haemorrhage: The usual dose is 5 IU slowly iv after delivery of the placenta. In women given oxytocin for induction or enhancement of labour, the infusion should be continued at an increased rate during the third stage of labour and for the next few hours thereafter.

Treatment of postpartum uterine haemorrhage: 5 IU slowly iv, followed in severe cases by iv infusion of a solution containing 5 to 20 IU of oxytocin in 500 ml of a non-hydrating diluent, run at the rate necessary to control uterine atony.

Incomplete, inevitable, or missed abortion: 5 IU slowly iv, if necessary followed by iv infusion at a rate of 20 to 40 mU/min or higher.

Because oxytocin possesses slight antidiuretic activity, its prolonged iv administration at high doses in conjunction with large volumes of fluid, as may be the case in the treatment of inevitable or missed abortion or in the management of postpartum haemorrhage, may cause water intoxication associated with hyponatraemia. To avoid this rare complication, the following precautions must be observed whenever high doses of oxytocin are administered over a long time: an electrolyte-containing diluent must be used (not dextrose); the volume of infused fluid should be kept low (by infusing oxytocin at a higher concentration than recommended for the induction or enhancement of labour at term); fluid intake by mouth must be restricted; a fluid balance chart should be kept, and serum electrolytes should be measured when electrolyte imbalance is suspected.

Children: Not applicable.
Elderly: Not applicable.
Storage and shelf-life:

Store between 2°C and 8°C. May be stored below 25°C for 6 months, but must then be discarded.

Shelf-life: Three years.