PATIENT INFORMATION LEAFLET FOR HUMAN USE

SCHEDULING STATUS:

S4

Oxytocin 10 IU/ml Cospharm concentrate for solution for infusion

Active substance

Oxytocin

Sugar free

Read all of this leaflet carefully before you are given Oxytocin 10 IU/ml Cospharm

- 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.
- Oxytocin 10 IU/ml Cospharm has been prescribed for you personally, and you should not share your medicine with other people.

What is in this leaflet

1. What is Oxytocin 10 IU/ml Cospharm and what it is used for
2. What you need to know before you are given Oxytocin 10 IU/ml Cospharm
3. How Oxytocin 10 IU/ml Cospharm must be administered
4. Possible side effects
5. How to store Oxytocin 10 IU/ml Cospharm
6. Contents of the pack and other information

1. What is Oxytocin 10 IU/ml Cospharm and what it is used for

This product contains a manufactured form of oxytocin (a natural hormone).

It belongs to a group of medicines called oxytocics that make the muscles of the womb contract.

Before birth

- To start or help on labour (childbirth) for medical reasons.
- Enhancement of labour in selected cases.
- Oxytocin 10 IU/ml Cospharm may be indicated in early stage of pregnancy, as management of miscarriage.

After birth

- During caesarean after the delivery of the child.
- Prevention and treatment of bleeding after delivery of the baby.

2. What you need to know before you are given Oxytocin 10 IU/ml Cospharm

Oxytocin 10 IU/ml Cospharm should not be administered to you

- if you are allergic (hypersensitive) to oxytocin or any of the other ingredients of Oxytocin 10 IU/ml Cospharm (listed in section 6)
- if you previously had a reaction to oxytocin
- if your doctor thinks that to start or increase contractions of the womb would be unsuitable for you, for example
  - where contractions of the womb are unusually strong
  - where there are obstructions that may prevent delivery
  - where your baby may be short of oxygen
- where labour or vaginal delivery is not advisable, for example:
  - if your baby's head is too large to fit through your pelvis
  - if your baby is wrongly positioned in the birth canal
  - if the placenta lies near or over the neck of your womb
  - if your baby lacks oxygen due to blood vessels running across the neck of your womb
  - if the placenta separates from the womb before the baby is born
  - if there are one or more loops of the umbilical cord between the baby and the neck of the womb, either before or after your water breaks
  - if your womb is over-extended and more likely to tear, for example if you are carrying more than one baby or have too much water (amniotic fluid) in your womb

- if you have had five or more pregnancies in the past or if your womb is scarred by previous caesarean section or other surgery

- if you have been given medicines called prostaglandins (used to bring on labour or treat stomach ulcers). Oxytocin 10 IU/ml Cospharm should not be used for 6 hours after vaginal prostaglandins as both the medicines may be increased.

Oxytocin 10 IU/ml Cospharm should not be used for prolonged periods if:

- your contractions do not increase with the treatment
- you have a condition known as severe pre-eclampsia (high blood pressure, protein in the urine and swelling)
- you have severe problems with your heart or blood circulation.

Warnings and precautions

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

Take special care with Oxytocin 10 IU/ml Cospharm

- If you are taking medicines for known “long QT syndrome” or medicines that are known to prolong the QTc interval on the electrocardiogram (ECG)
- If you had previous caesarean section
- You are older than 35 years old
- You have raised blood pressure or heart problems/disease
- Your womb was contracting strongly but has now begun to contract less strongly
- You have kidney problems, as this product can cause water retention
- You have had complications during your pregnancy
- You are more than 40 weeks pregnant
- You have been told by a doctor or midwife that normal delivery may be difficult for you due to the small size of your pelvis.

If any of the above applies to you, or if you are not sure, speak to your doctor or midwife before you receive Oxytocin 10 IU/ml Cospharm

Special care should be taken with Oxytocin 10 IU/ml Cospharm

- Oxytocin 10 IU/ml Cospharm should only be used for medical reasons and not for convenience.

- Oxytocin 10 IU/ml Cospharm should only be administered in hospital under supervision of a qualified healthcare professional.
- Oxytocin 10 IU/ml Cospharm should only be administered as an i.v infusion and not as an injection.

Latex allergy

The active substance in Oxytocin 10 IU/ml Cospharm might cause a severe allergic reaction (anaphylaxis) in patients with latex allergy.

Please tell your doctor if you know you are allergic to latex.

Other medicines and Oxytocin 10 IU/ml Cospharm

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

(This includes all complementary or traditional medicines).

- Medicines that prolong the QTc interval (for e.g. amiodarone, amantadine, salbutamol, clarithromycin, domperidone etc.).
- Prostaglandins (used to start labour or to treat stomach ulcers) as the effect of both drugs may be increased.
- Anaesthetics which you breathe in (e.g. to put you to sleep during surgery) such as halothane, cyclopropane, sevoflurane or desflurane as the these may weaken your contractions, cause problems with your heartbeat or increase the blood pressure lowering effects of Oxytocin 10 IU/ml.
- Anaesthetic medicines for local or regional pain relief, in particular an epidural for pain relief during labour. Oxytocin 10 IU/ml Cospharm may increase the blood vessel narrowing effect of these medicines and cause an increase in blood pressure.

Oxytocin 10 IU/ml Cospharm with food and drink and alcohol

- You may be told to keep the amount of fluids you drink to a minimum.

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, Please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

It is not expected that Oxytocin 10 IU/ml Cospharm would be a risk to your baby when used correctly.

Oxytocin 10 IU/ml Cospharm may be found in small amounts in breast milk but is not expected to have harmful effects in your baby.

Driving and using machines

Oxytocin 10 IU/ml Cospharm can induce labor, therefore caution should be exercised when driving or operating machines. Women with uterine contractions should not drive or use machines.

Oxytocin 10 IU/ml Cospharm contains 0,0061 ml of alcohol (ethanol) per ampoule. The amount of alcohol in this medicine is not likely to have an effect in adults. The alcohol in this medicine may alter the effects of other medicines.

3. How Oxytocin 10 IU/ml Cospharm must be administered

You will not be expected to give yourself Oxytocin 10 IU/ml Cospharm

It will be given to you by a person who is qualified to do so.

Your doctor or midwife will decide when and how to treat you with Oxytocin 10 IU/ml Cospharm. If you think that the effect of Oxytocin 10 IU/ml Cospharm are to strong or too weak, tell your doctor or midwife. While you are receiving Oxytocin 10 IU/ml Cospharm, both you and your baby will be closely monitored.

Oxytocin 10 IU/ml Cospharm is usually diluted before use and given as an intravenous infusion (drip) into one of your veins.

If you take more Oxytocin 10 IU/ml Cospharm than you should

Since a healthcare provider will administer Oxytocin 10 IU/ml Cospharm, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take Oxytocin 10 IU/ml Cospharm

Since a healthcare provider will administer Oxytocin 10 IU/ml Cospharm, it is unlikely that the dose will be missed.

If you stop using Oxytocin 10 IU/ml Cospharm

Since a healthcare provider will administer Oxytocin 10 IU/ml Cospharm, it is unlikely that the dose will be stopped before the end of treatment regimen.

4. Possible side effects

Oxytocin 10 IU/ml Cospharm can have side effects.

Not all side effects reported for Oxytocin 10 IU/ml Cospharm are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Oxytocin 10 IU/ml Cospharm, please consult your healthcare provider for advice.

If any of the following happens, stop using Oxytocin 10 IU/ml Cospharm and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- Rash or itching,
- Fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to Oxytocin 10 IU/ml Cospharm.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain,
- angina,
- changes in the way your heart beats, for example, if you notice it beating faster,
- difficulty breathing,
- signs of recurrent infections such as fever or sore throat,
- less urine than is normal for you,
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side-effects

- feeling nauseous
- headache

- fast or slow heart rate
- bleeding

Less frequent side- effects

- irregular heartbeat
- skin rashes
- severe allergic reaction causing dizziness, lightheadedness, difficulty in breathing
- swelling of the face, lips, tongue, throat, and/or extremities (possible signs of angioedema).

Frequency not known

- distress of the foetus, lack of oxygen and blood flow to brain of the foetus, death
- water intoxication, drop of sodium levels in the mother
- acute pulmonary oedema which is a build-up of fluid in the lungs and causes difficulty in breathing
- flushing, which can cause the skin to become red and hot
- abnormal blood clotting.

Other side effects

Effects in the mother

- haemorrhage (bleeding)
- chest pain (angina)
- irregular heartbeat
- excessive or continuous contractions
- tearing of the womb
- fluid retention (water intoxication). Symptoms may include headache, anorexia (loss of appetite), feeling or being sick, stomach pain, sluggishness, drowsiness, unconsciousness, low levels of certain chemicals in the blood (e.g. sodium or potassium), fits

- low blood salt levels
- sudden fluid overload in the lungs
- sudden brief sensation of heat often over the whole body
- abnormal clotting, bleeding and anaemia
- spasm of the muscles of the womb

Effects in the baby

- Excessive contractions may cause low blood salt levels, shortage of oxygen, suffocation and death.

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 or 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 affects you can help provide more information on the safety of Oxytocin 10 IU/ml Cospharm.

You should also report side effects to the Holder of Certificate of Registration:

Cospharm Investments (Pty) Ltd.

The contact details for our national reporting system are:

Email: rp@cospharm.org

5. How to store Oxytocin 10 IU/ml Cospharm

Store all medicines out of reach of children.

Since a healthcare provider will administer Oxytocin 10 IU/ml Cospharm he/she will ensure the following storage conditions are met.

Store in a refrigerator between 2 °C and 8 °C.

Protect from direct light.

The medicine will be disposed by the healthcare professional.

6. Contents of the pack and other information

What Oxytocin 10 IU/ml Cospharm contains

The active substance is Oxytocin 10 IU/ml

The other ingredients are:

Chlorobutanol 0,5 % w/v (preservative)

Ethanol (96 %)

Glacial acetic acid

Sodium acetate trihydrate

Sodium chloride

Water for injection

What Oxytocin 10 IU/ml Cospharm looks like and contents of the pack

Oxytocin 10 IU/ml Cospharm is a clear colourless solution free from visible particulate filled in 1 ml clear glass ampoules (USP type I).

5 or 10 Ampoules are packed in a plastic ampoule tray.

Holder of Certificate of Registration

Cospharm Investments (Pty) Ltd.

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This leaflet was last revised in

16 May 2023

Registration number

55/19/0705