PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

OXYJECT solution for injection. Oxytocin

10 IU/ml.

Read all of this leaflet carefully before you are given OXYJECT.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

What is in this leaflet

1. What OXYJECT is and what it is used for

2. What you need to know before you are given OXYJECT

3. How OXYJECT should be given to you

4. Possible side effects

5. How to store OXYJECT

6. Contents of the pack and other information

1. What OXYJECT is and what it is used for

OXYJECT contains a medicine called oxytocin which 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 (childbirth) in selected cases.
- OXYJECT may also be indicated in early stage of pregnancy, as management of miscarriage.

After birth

- During caesarean section, 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 OXYJECT You should not be given OXYJECT

- If you are allergic (hypersensitive) to the active substance, oxytocin, or to any of the other ingredients of OXYJECT listed in section 6. 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 umbilical cord between the baby and the neck of the womb, either before or after your waters break
  - 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). OXYJECT should not be used for 6 hours after vaginal prostaglandins as the effects of both medicines may be increased.

- OXYJECT 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

If you think any of these apply to you, or if you are in any doubt at all, tell your doctor before being given OXYJECT.

Warnings and precautions

OXYJECT should only be administered by a healthcare professional in a hospital setting. OXYJECT should not be given as a rapid injection into a vein as this may cause low blood pressure, a sudden brief sensation of heat (often over the entire body), and an increased heart rate.

Tell your doctor or healthcare professional before being given OXYJECT:

- If you are prone to chest pain due to pre-existing heart and/or circulation problems.
- If you have a known irregular heartbeat (“long QT syndrome”) or related symptoms or are taking medicines that are known for "long QT syndrome" or medicines that are known to prolong the QTc interval on the Electrocardiogram (ECG).
- If your womb was contracting strongly but has now begun to contract less strongly.
- If you have had a previous caesarean section.
- If you are older than 35 years.
- If you have raised blood pressure or heart problems/disease.
- If 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 you have had complications during your pregnancy.
- If you are more than 40 weeks pregnant.
- If you have kidney problems, as OXYJECT can cause water retention.

When OXYJECT is given to induce and enhance labour, the infusion rate should be set to maintain a contraction pattern similar to normal labour and adjusted to individual response. Too high doses may cause very strong continuous and possibly tearing of the womb, with serious complications for you and your baby.

OXYJECT may cause disseminated intravascular coagulation which causes symptoms including abnormal blood clotting, bleeding and anaemia.

Large doses of OXYJECT over a long period of time, whilst drinking or receiving large volumes of fluid may make your stomach feel very full, cause difficulty in breathing and lower salt levels in your blood.

Latex allergy

The active substance in OXYJECT 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 OXYJECT:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of OXYJECT with these medicines may cause undesirable interactions.

Please consult your doctor, pharmacist or other health care professional for advice if you are taking any of the following:

- prostaglandins (used to start labour or to treat stomach ulcers) as the effects of both medicines may be increased
- medicines that can cause an irregular heartbeat as OXYJECT may increase this effect
- anaesthetics which you breathe in (e.g. to put you to sleep during surgery), such as cyclopropane, halothane, sevoflurane or desflurane) as these may weaken your contractions, or cause problems with your heartbeat
- anaesthetic medicines for local or regional pain relief, in particular an epidural for pain relief during labour. OXYJECT may increase the blood vessel narrowing effect of these medicines and cause an increase in blood pressure.

OXYJECT with food and drink

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before being given OXYJECT.

OXYJECT is unlikely to present a risk of abnormalities in an unborn baby when used as prescribed.

Oxytocin may be found in small quantities in mother's breast milk. However, it is unlikely to cause harmful effects in the newborn.

Driving and using machines

OXYJECT can induce/start labour, therefore caution should be exercised when driving or operating machines. Women with uterine contractions should not drive or use machines.

3. How OXYJECT should be given to you

You will not be expected to give yourself OXYJECT. It will be given to you by a person who is qualified to do so. OXYJECT is usually diluted before use and given as an intravenous infusion (drip) into one of your veins. Your doctor will decide the correct dose for you and for how it should be given.

If you are given more OXYJECT than the recommended dose

The treatment schedule and dosage will be set by your doctor, who will monitor your response and condition.

When signs or symptoms of overdosage occur during continuous intravenous (I.V.) administration of OXYJECT, the infusion will be discontinued at once and oxygen will be given to the mother.

An overdose of OXYJECT could cause:

- Very strong contractions of the womb
- Damage to your womb which could include tearing
- The placenta to come away from your womb
- Amniotic fluid (the fluid around the baby) enters your bloodstream
- Painful, spastic, sustained muscle contraction
- Bleeding in your brain
- A fall in blood pressure causing dizziness, light headedness or feeling faint
- Fluid build-up inside your body known as fluid retention. Your stomach may feel full, and you may have difficulty breathing

- Fits
- Coma
- Harm to the baby due to lack of oxygen

If you have missed a dose of OXYJECT:

Since a healthcare professional will administer OXYJECT, it is unlikely that the dose will be missed. If you are concerned that you may have missed a dose, contact your doctor or another healthcare professional immediately.

4. Possible side effects

OXYJECT can have side effects.

Not all side effects reported for OXYJECT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking OXYJECT, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens after receiving OXYJECT, tell your doctor immediately:

- a severe allergic (anaphylactic/anaphylactoid) reaction with difficulty in breathing, dizziness and lightheadedness, feeling faint, nausea, cold and clammy skin or a fast or weak pulse,
- swelling of the face, lips, tongue, throat, and/or extremities (possible signs of angioedema).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to OXYJECT. You may need urgent medical attention.

The following side effects can occur frequently while receiving OXYJECT:

- headache.
- fast or slow heartbeat.
- low blood pressure.
- nausea.
- vomiting.
- flushing.

The following side effects can occur during treatment with OXYJECT and is seen less frequently:

- irregular heartbeat
- skin rash

Other effects on the mother include:

- excessive or continuous contractions
- tearing of the womb
- Spasm of the muscles of the womb
- abnormal clotting, bleeding and anaemia
- fluid retention (water intoxication). Symptoms may include headache, anorexia (loss of appetite), nausea, vomiting, stomach pain, sluggishness, drowsiness, unconsciousness, seizures (fits), low levels of certain chemicals in the blood (e.g. sodium or potassium)

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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 effects, you can help provide more information on the safety of OXYJECT.

5. How to store OXYJECT

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- The hospital pharmacy will store OXYJECT in a refrigerator between 2 ˚C – 8 ˚C and make sure that it does not freeze and are not used after the expiry date on the pack.

6. Contents of the pack and other information

What OXYJECT contains

The active substance is oxytocin.

Each ampoule contains 10 IU/ml oxytocin.

Excipients with known effect:

Each vial contains 1 mg of sodium acetate as buffering agent.

The other ingredients are glacial acetic acid, sodium acetate and water for injection.

What OXYJECT looks like and contents of the pack

OXYJECT is a clear colourless solution.

OXYJECT solution for injection is packed as 10 x 1 ml Type 1 borosilicate glass, clear ampoule packed in a clear PVC pocket ampoule. The pocket of 10 ampoules are packed in an outer carton.

Holder of Certificate of Registration and Manufacturer

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This leaflet was last revised in

12 July 2022

Registration numbers

52/19/0903.902