1.3.2 CLEAN PROPOSED AMENDED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

SYNTOMETRINE®, Injection

Ergometrine maleate and Oxytocin

Sugar free

Read all of this leaflet carefully before you are given SYNTOMETRINE®

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

What is in this leaflet

1. What SYNTOMETRINE® is and what it is used for

During labour:

Active management of the third stage of labour (as a means to promote childbirth and to reduce blood loss).

After labour:

Prevention and treatment of bleeding after delivery of the baby.

2. What you need to know before you are treated with SYNTOMETRINE®

You should not be administered SYNTOMETRINE® if:

- You are allergic to ergometrine maleate or oxytocin or to any other ingredients of SYNTOMETRINE® (listed in section 6)
- You are not in labour or are in the first or second stages of labour
- You have ineffective contractions
- You have had a previous caesarean section
- You have impaired kidney or liver function
- You have high blood pressure that may or may not result in fits
- The foetus is in distress
- You have porphyria (metabolic disease affecting porphyrin metabolism)
- You have occlusive vascular disease (blockage or narrowing of an artery resulting in pain usually in the legs)
- You have sepsis (a condition that may occur after an infection and results in fever, difficulty breathing, low blood pressure, fast heart rate and mental confusion)
- You have any heart conditions

Warnings and precautions

Tell your doctor or healthcare professional before being given the injection if:

- If you have Raynaud's phenomenon (a condition in which spasms of the blood vessels causes reduced blood flow resulting in numbness, pain and discolouration).
- If you have suffered any heart problems including 'long QT syndrome' (irregular heartbeats) and narrowing of the blood vessels.

Other medicines and SYNTOMETRINE®:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

In particular, tell your doctor if you are taking or received:

- Any medicines used to treat heart problems or blood pressure problems.
- Any local or inhaled anaesthetics.
- Any antibiotics or antifungals (medicines used to treat bacterial or fungal infections).
- Any medicines for the treatment of HIV-infection.
- Any medicine used to treat headaches or migraines.

Pregnancy, breastfeeding and fertility:

The use of SYNTOMETRINE® in pregnancy, first or second stage of labour is not recommended.

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 health care provider for advice before taking this medicine.

Driving and using machines:

SYNTOMETRINE® treatment may affect your ability to drive or operate machinery.

Taking SYNTOMETRINE® can start labour. If you have contractions, you should not drive or use machines.

You may experience dizziness and low blood pressure. If affected you should not drive or use machinery.

3. How to receive SYNTOMETRINE®

SYNTOMETRINE® will be administered to you by a healthcare professional.

Your doctor will tell you how long your treatment with SYNTOMETRINE® will last.

You will not be expected to give yourself SYNTOMETRINE®. It will be given to you by a person who is qualified to do so.

During labour:

SYNTOMETRINE® will be injected into a muscle after delivery of the shoulder, or at the latest, immediately after delivery of the child.

After labour:

SYNTOMETRINE® will be injected into a muscle or vein after delivery of the child.

If you use more SYNTOMETRINE® than you should

If you have the impression that SYNTOMETRINE® is too strong or too weak for you, please discuss this with your treating doctor.

Since a healthcare professional will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take SYNTOMETRINE®

Since a health care provider will administer SYNTOMETRINE®, it is unlikely that the dose will be missed.

4. Possible side effects

SYNTOMETRINE® can have side effects.

Not all side effects reported for SYNTOMETRINE® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SYNTOMETRINE®, please consult your health care provider for advice.

If any of the following happens, stop receiving SYNTOMETRINE® and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- skin rash or itching
- itching and redness of your eyes
- fainting
- chest tightness or difficulty in breathing

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

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

- Pain and tightness in your chest and difficulty breathing.
- Swelling of any parts of your body.

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

Tell your doctor if you notice any of the following:

- A rise in your blood pressure which may cause the following: severe headache, chest pain, difficulty breathing, vision problems, changes in the way your heart beats, for example, if you notice it beating faster
- Nausea, vomiting or stomach pains.

- Pelvic haematomas (blood clots in the lower part if the stomach causing pain, fever, and foul-smelling discharge).
- Headache or dizziness

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. 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 SYNTOMETRINE®.

For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email Adcock.aereports@adcock.com

5. How to store SYNTOMETRINE®

Store in a refrigerator between 2 to 8 °C.

Do not freeze.

Protect from light.

Do not remove the outer container until required for use.

SYNTOMETRINE® SHOULD BE KEPT OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What SYNTOMETRINE® contains:

The active substances are Ergometrine maleate and Oxytocin

The other ingredients are:

- Chlorobutanol hemihydrate
- Glacial acetic acid
- Maleic acid
- Nitrogen,
- Sodium acetate
- Sodium chloride
- Water for injection

What SYNTOMETRINE® looks like and contents of the pack

A 1 ml clear glass ampoule coded with two green-coloured rings on the neck of the ampoule.

5 ampoules of 1 ml in a carton**.**

Holder of Certificate of Registration

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