1.3.2 Patient Information Leaflet

1.5.5.2 Patient Information Leaflet **-CLEAN**

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

SYNTOCINON 5 IU®

SYNTOCINON 10 IU®

Injection

Oxytocin

This medicine contains 2,99 mg (0,13 mmol), less than 1 mmol sodium (23 mg) per 1 ml that is to say essentially 'sodium free'.

Sugar free.

Read all of this leaflet carefully before you start using SYNTOCINON

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare professional.
- It will only be administered in a hospital setting under qualified medical supervision (see section 3).

What is in this leaflet

1. What SYNTOCINON is and what it is used for.

2. What you need to know before you take/use SYNTOCINON.

1.3.2 Patient Information Leaflet

1.5.5.2 Patient Information Leaflet **-CLEAN**

3. How to take/use SYNTOCINON.

4. Possible side effects.

5. How to store SYNTOCINON.

6. Contents of the pack and other information.

1. What SYNTOCINON is and what it is used for

What SYNTOCINON is:

SYNTOCINON belongs to a group of medicines called oxytocics that makes the muscles of the womb contract.

What SYNTOCINON is used for:

Before birth

- To induce labour (childbirth) for medical reasons.
- Enhancement of labour (childbirth) in selected cases.
- SYNTOCINON 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.

1.3.2 Patient Information Leaflet

1.5.5.2 Patient Information Leaflet **-CLEAN**

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

SYNTOCINON should not be administered to you:

- If you have a known allergy or if you are hypersensitive (allergic) to oxytocin or to any of the other ingredients of SYNTOCINON (listed in *section 6.1*).
- If you previously had a reaction to SYNTOCINON injection.
- If your doctor thinks that to start or increase contractions of the womb would be unsuitable for you, for example where:
  - The contractions of the womb are unusually strong.
  - There may be an oxygen shortage to your baby.
  - There are obstructions preventing delivery.
- If labour or vaginal delivery is not advisable, for example where:
  - The baby's head may be too large to fit through your pelvis.
  - The baby is incorrectly positioned in the birth canal.
  - The placenta is wrongly positioned or separates from the womb.
  - The oxygen shortage occurs due to blood vessels passing near to the cervix (the lower, narrow end of the uterus that forms a canal between the uterus and vagina).
  - Parts of the umbilical cord are present between the baby and the cervix (before or after your water breaks).
  - You have too much amniotic fluid (important fluid for you baby's development).
  - You have had previous pregnancies and/or your womb is scarred from previous caesarean section.

1.3.2 Patient Information Leaflet

1.5.5.2 Patient Information Leaflet **-CLEAN**

Warnings and precautions

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

- you have a known irregular heartbeat ('long QT syndrome') or you are taking medicines that are known for "long QT syndrome" or medicines that are known to prolong the QTc interval on the Electrocardiogram (ECG);
- you are allergic to latex, as this can result in severe allergic reactions when receiving SYNTOCINON;
- you have had a previous caesarean section;
- you have a small pelvis;
- you have liver or kidney problems as SYNTOCINON can cause water retention (fluid build-up in your body);
- you are older than 35 years;
- you have raised blood pressure, heart problems/disease, circulation problems or are prone to chest pain;
- your womb was contracting strongly but has now begun to contract less strongly;
- you had complications during your pregnancy;
- you are more than 40 weeks pregnant.

If any of the above applies to you, or if you are not sure, speak to your doctor or midwife before you receive SYNTOCINON.

1.3.2 Patient Information Leaflet

1.5.5.2 Patient Information Leaflet **-CLEAN**

Take special care with SYNTOCINON:

- While drinking large volumes of water, as it can result in water intoxication with low doses of sodium in your blood.
- SYNTOCINON should only be used for medical reasons and not for convenience.
- SYNTOCINON should only be administrated in hospital under supervision of a qualified healthcare professional.
- SYNTOCINON should only be administrated as an IV infusion and not as a rapid injection into the vein as this may cause low blood pressure, a sudden brief sensation of heat (often over the entire body), and an increased heart rate.
- SYNTOCINON can cause a rare but serious condition that causes abnormal blood clotting, bleeding and anaemia (shortage of oxygen). This increases if the women has additional risk factors for this condition.
- SYNTOCINON in high doses can cause amniotic fluid to move from your womb into your blood (known as amniotic fluid embolism), and can result in heart failure in your baby.

SYNTOCINON should not be used for prolonged periods if:

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

1.3.2 Patient Information Leaflet

1.5.5.2 Patient Information Leaflet **-CLEAN**

Other medicines and SYNTOCINON

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines). The use of SYNTOCINON with these medicines may cause undesirable interactions.

Tell your doctor if you are taking any of the following 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 effects of both medicines may be increased.
- Medicines used to induce labour and reduce bleeding after birth (for example sulprostone or methylergometrine), as concomitant use with SYNTOCINON may cause irregular heartbeat/heart problems, sometimes fatal.
- Inhalation anaesthetics such as cyclopropane, halothane, sevoflurane and desflurane (medicines used to help you sleep during surgery) may weaken your contractions or cause problems with your heartbeat.

- Medicines used for local or regional pain relief (vasoconstrictors and sympathomimetics) in concomitant use with SYNTOCINON, may increase the blood vessel narrowing effect and results in higher blood pressure.
- Medicines used to treat high blood pressure, as SYNTOCINON can

1.3.2 Patient Information Leaflet

1.5.5.2 Patient Information Leaflet **-CLEAN**

increase this effect.

SYNTOCINON with food and drink and alcohol

SYNTOCINON will be administered in a hospital setting under qualified medical supervision. You may be advised to limit the amount of fluid intake *(see section 'Take special care with SYNTOCINON').*

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please inform your doctor or healthcare professional.

It is not expected that SYNTOCINON would be a risk to your baby when used as indicated. SYNTOCINON may be found in small quantities in breast milk but is not expected to have harmful effects on your baby because it is inactivated in his/her body.

Driving and using machinery

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

SYNTOCINON contains:

SYNTOCINON contains alcohol: ethanol 96 % *w/w* (as solvent).

SYNTOCINON contains sodium:

1.3.2 Patient Information Leaflet

1.5.5.2 Patient Information Leaflet **-CLEAN**

This medicine contains 2,99 mg (0,13 mmol), less than 1 mmol sodium (23 mg) per 1 ml that is to say essentially 'sodium free'.

SYNTOCINON is sugar free.

3. How to receive SYNTOCINON

SYNTOCINON will only be administered in a hospital setting under qualified medical supervision.

Do not share medicines prescribed for you with any other person.

The dose you will receive is different in the following circumstances:

- To start or help contractions during labour.
- Miscarriage.
- Caesarean section.
- Prevention/treatment of bleeding after delivery.
- Incomplete, inevitable or missed abortion.

Duration of treatment

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

If you have the impression that the effect of SYNTOCINON is too strong or too weak, tell your doctor or pharmacist.

Method of administration

1.3.2 Patient Information Leaflet

1.5.5.2 Patient Information Leaflet **-CLEAN**

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

Dosage in patients with kidney or liver impairment:

If you have kidneys/liver that does not function normally, please consult your doctor.

If you are given more SYNTOCINON than you should

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

If you missed a dose of SYNTOCINON

Since a healthcare professional will administer SYNTOCINON, it is unlikely that the dose will be missed.

4. Possible side effects

SYNTOCINON can have side effects.

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

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

1.3.2 Patient Information Leaflet

1.5.5.2 Patient Information Leaflet **-CLEAN**

- Swelling of the hands, feet, ankles, face, lips, 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 allergic reaction to SYNTOCINON. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- feeling nauseous and vomiting;
- headache;
- fast or slow heart rate;
- low blood pressure;
- shock;
- flushing;
- bleeding.

The following side effects have been reported less frequently:

- irregular heartbeat;
- increase in blood pressure;
- skin rashes;

1.3.2 Patient Information Leaflet

1.5.5.2 Patient Information Leaflet **-CLEAN**

- severe allergic reaction (anaphylaxis) causing dizziness, lightheadedness, difficulty breathing, low blood pressure and shock.

The following side effects have been reported but the frequency is unknown:

- Disseminated intravascular coagulation (DIC), a rare but serious condition that causes abnormal blood clotting throughout the body's blood vessels.
- Swelling of the deeper layers of the skin caused by a build-up of fluid in the body (angioedema).
- Increased fluid intake (water intoxication) can cause loss of sodium in the mother and baby.
- Reduced blood flow to the heart resulting in loss of oxygen.
- QTc prolongation (irregular heartbeat).
- Decrease in blood pressure.
- Hot flushes.
- Foetal distress (baby experiences distress during labour).
- A condition where the body is deprived of oxygen (asphyxia).
- Sudden fluid overload in lungs.
- Spasm of the muscles of the womb.
- Contractions or rupture of the womb.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

1.3.2 Patient Information Leaflet

1.5.5.2 Patient Information Leaflet **-CLEAN**

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions 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 SYNTOCINON.

5. How to store SYNTOCINON

Store all medicines out of reach of children.

Store at or between 2 °C – 8 °C (in a refrigerator).

Store in the original package / container.

Keep the container in the outer carton.

Protect from direct light.

Do not store in a bathroom.

Do not use after the expiry date stated on the label / carton / bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SYNTOCINON contains:

SYNTOCINON 5 IU®:

1.3.2 Patient Information Leaflet

1.5.5.2 Patient Information Leaflet **-CLEAN**

The active substance is: Each 1 ml ampoule (concentrate for solution for infusion, solution for injection) contains 5 IU synthetic oxytocin.

The other ingredients are: Acetic acid, glacial; chlorobutanol hemihydrate 0,5 % *m/v* (as preservative); ethanol 96 % *w/w* (alcohol as solvent); sodium acetate, trihydrate; water for injection.

SYNTOCINON 10 IU®:

The active substance is: Each 1 ml ampoule (concentrate for solution for infusion, solution for injection) contains 10 IU synthetic oxytocin.

The other ingredients are: Acetic acid, glacial; chlorobutanol hemihydrate 0,5 % *m/v* (as preservative); ethanol 96 % *w/w* (alcohol as solvent); sodium acetate, trihydrate; water for injection.

What SYNTOCINON looks like and contents of the pack:

SYNTOCINON 5 IU®

A clear, colourless solution in a 1 ml clear glass ampoule coded with a single magenta-coloured ring on the neck of the ampoule.

Pack sizes: Carton of 5 ampoules of 1 ml each.

SYNTOCINON 10 IU®

A clear, colourless solution in a 1 ml clear glass ampoule, coded with two magenta-coloured rings on the neck of the ampoule.

Pack sizes: Carton of 5 ampoules of 1 ml each.

1.3.2 Patient Information Leaflet

1.5.5.2 Patient Information Leaflet **-CLEAN**

Holder of Certificate of Registration and Manufacturer

Viatris Healthcare (Pty) Ltd

4 Brewery Street

Isando

Gauteng

1601

This leaflet was last revised in

Date of publication: 20 April 2012

Date of revision of text: TBA

Registration number

SYNTOCINON 5 IU®: H/19/1967

SYNTOCINON 10 IU®: H/19/1963

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website.