WHO-PQ RECOMMENDED
PATIENT INFORMATION LEAFLET

This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities (term to be revised).
The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

Information for the patient

[RH083 trade name] [1]
oxytocin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness seem to be the same as yours.
- If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [RH083 trade name] is and what it is used for

[RH083 trade name] 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.

[RH083 trade name] is used:

- To start or help contractions during childbirth (labour)
- To help in the management of miscarriage
- During a caesarian section
- To prevent and control bleeding after delivery of your baby

2. What you need to know before you are given [RH083 trade name]

You must not receive [RH083 trade name]:

- If you are allergic to oxytocin or any of the other ingredients of this medicine (listed in section 6)
- If your healthcare provider 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 your placenta lies near or over the neck of your womb

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

- If your 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 caesarian section or other surgery

- If you have been given medicines called prostaglandins (used to bring on labour or treat stomach ulcers). [RH083 trade name] should not be used for 6 hours after vaginal prostaglandins as the effects of both medicines may be increased

[RH083 trade name] 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

Warnings and precautions:

[RH083 trade name] should only be administered by a healthcare provider in a hospital setting.

[RH083 trade name] should not be given as a rapid injection into a vein as this may cause decreased blood pressure, a sudden brief sensation of heat (often over the entire body) and an increased heart rate.

Talk to your healthcare provider before you receive [RH083 trade name] if:

- You are prone to chest pain due to pre-existing heart and/or circulation problems
- You have a known irregular heartbeat ('long QT syndrome') or related symptoms, or are taking medicines known to cause the syndrome (see section on 'Other medicines and [RH083 trade name]')
- You have had a previous caesarian section
- You are more than 35 years old
- You have raised blood pressure or heart problems
- Your womb was contracting strongly but has now begun to contract less strongly
- You have been told by a healthcare provider that normal delivery may be difficult for you due to the small size of your pelvis
- You have kidney problems, as oxytocin may cause water retention
- You have had complications during your pregnancy
- You are more than 40 weeks pregnant

When [RH083 trade name] is given to induce and enhance labour, the infusion rate should be set to maintain a contraction pattern similar to normal labour and adjusted according to individual response. Too high doses may cause very strong continuous contractions and possibly tearing of the womb, with serious complications for you and your baby.

[RH083 trade name] may cause disseminated intravascular coagulation which causes symptoms including abnormal blood clotting, bleeding and anaemia. High doses of [RH083 trade name] may force amniotic fluid from your womb into your blood. This is known as amniotic fluid embolism.

Large doses of [RH083 trade name] 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.

If any of the above apply to you, or if you are not sure, speak to your healthcare provider before you receive [RH083 trade name].

Latex allergy:

The active substance in [RH083 trade name] might cause a severe allergic reaction (anaphylaxis) in patients with latex allergy. Please tell your healthcare provider if you know you are allergic to latex.

Children and adolescents:

[RH083 trade name] is not intended for use in children or adolescents.

Other medications and [RH083 trade name]:

Tell your healthcare provider if you are taking or have recently taken any of the following medicines as they may interfere with [RH083 trade name]:

- Prostaglandins (used to start labour or to treat stomach ulcers) and similar drugs as the effects of both drugs may be increased
- Medicines that can cause an irregular heartbeat, as oxytocin may increase this effect
- Anaesthetics which you breath in (e.g. to put you to sleep during surgery), such as halothane, cyclopropane, 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. Oxytocin may increase the blood vessel narrowing effect of these medicines and cause an increase in blood pressure.

Please tell your healthcare provider if you are taking or have recently taken or might take any other medicines.

[RH083 trade name] with food and drink:

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

Pregnancy, breastfeeding and fertility:

Based on the wide experience of use and the nature of this medicine, it is not expected that [RH083 trade name] would be a risk to your baby when used correctly.

Oxytocin may be found in small amounts in breast milk but is not expected to have harmful effects because it is quickly inactivated by your baby's digestive system. The effects of oxytocin on fertility are unknown.

Driving and using machines:

[RH083 trade name] can start labour. Women with uterine contractions should not drive or use machines.

[RH083 trade name] contains ethanol and sodium

[RH083 trade name] contains small amounts of ethanol (alcohol), less than 100 mg per mL (0.005 mg). The small amount of alcohol in this medicine will not have any noticeable effects.

[RH083 trade name] also contains less than 1 mmol sodium (23 mg) per mL, that is to say essentially 'sodium-free' (0.176 mg / 0.0073 mmol).

3. How [RH083 trade name] is given

[RH083 trade name] should only be given under medical supervision and in a hospital.

Your healthcare provider will decide when and how to treat you with [RH083 trade name]. If you think that the effect of [RH083 trade name] is too strong or too weak, tell your healthcare provider. While you are receiving [RH083 trade name], both you and your baby will be closely monitored.

[RH083 trade name] is usually diluted before use and given as an intravenous infusion (drip) into one of your veins.

The usual dose is different in the following circumstances:

To start or help contractions during labour:

The rate of infusion will start at 2 to 8 drops per minute. This may be gradually increased to a maximum rate of 40 drops per minute. The infusion rate can often be reduced once the contractions reach an adequate level, about 3 to 4 contractions every 10 minutes.

If your contractions do not reach the adequate level after 5 IU (8.3 micrograms), the attempt to start labour should be stopped and then repeated the following day.

Miscarriage:

The dose is 5 IU (8.3 micrograms) by infusion into a vein. In some cases, this may be followed by a drip at 40 to 80 drops per minute.

Caesarean section:

The dose is 5 IU (8.3 micrograms) by infusion into a vein immediately after delivery of your baby.

Prevention of bleeding after delivery:

The dose is 5 IU (8.3 micrograms) by infusion into a vein after delivery of the placenta.

Treatment of bleeding after delivery:

The dose is 5 IU (8.3 micrograms) by infusion into a vein. In some cases, this may be followed by a drip containing 5 to 20 IU (8.3 to 33.4 micrograms) of oxytocin.

Older people (65 years and over):

[RH083 trade name] is not intended for use in elderly.

Patients with kidney disease:

There is no information on use in patients with kidney disease. However, you should tell your healthcare provider if you suffer from kidney problems (see section 2).

Patients with liver disease:

There is no information on use in patients with liver disease.

If you receive more [RH083 trade name] *than you should:*

As this medicine is given to you in hospital, it is very unlikely that you will receive an overdose.

If anyone accidentally receives this medicine, tell the hospital accident and emergency department or a doctor immediately. Show any left-over medicines or the empty packet to the doctor.

An overdose of [RH083 trade name] could cause:

- Very strong contractions of your womb
- Damage to your womb which could include tearing
- The placenta to come away from your womb
- Amniotic fluid (the fluid around the baby) to enter your bloodstream
- Harm to your baby

If you miss a dose of [RH083 trade name]:

As a healthcare provider is giving you this medicine, you are unlikely to miss a dose.

If you have any further questions on the use of this medicine, ask your healthcare provider.

4. Possible side effects

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

Common side effects (affects more than 1 in 100 patients):

- Headache
- Fast or slow heartbeat
- Feeling or being sick

Uncommon side effects (affects more than 1 in 1000 patients):

- An irregular heartbeat

Rare side effects (affects more than 1 in 10,000 patents):

- A severe allergic reaction with difficulty breathing, dizziness and light-headedness, feeling faint, nausea, cold and clammy skin or a fast or weak pulse
- Rash

Other side effects

Effects in the mother:

Not known (cannot be estimated from the available data):

- Chest pain (angina)
- Irregular heartbeat (QTc prolongation seen on electrocardiogram)
- Low blood pressure
- Haemorrhage (bleeding)
- Increased uterine tone
- 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 over the whole body
- Abnormal blood clotting, bleeding or anaemia (disseminated intravascular coagulation

Effects in the baby:

Not known (cannot be estimated from the available data):

Excessive contractions may cause:

- Shortage of oxygen, suffocation and death
- Low blood salt levels

Reporting of side effects

If you get any side effects,talk to your health care provider.This includes unwanted effects not listed in this leaflet.If available, you can also report side effects directly through the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [RH083 trade name]

Store in a refrigerator (2^{o}C to 8°C) in the original carton, protected from light. Do not freeze.

Keep this medicine out of the sight and reach of children.

This medicine must not be used after the expiry date stated on the label. The expiry date refers to the last day of that month.

This medicine must not be used if there are visible particles in the solution.

Do not throw away any medicines in wastewater. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [RH083 trade name] contains

- The active ingredient is oxytocin
- The other ingredients of [RH083 trade name] are ethanol, chlorobutanol, sodium acetate trihydrate, sodium chloride, glacial acetic acid, water for injections

What [RH083 trade name] looks like and contents of the pack

[RH083 trade name] is a clear colourless solution, contained in clear type I glass ampoule.

Pack sizes: 5, 10 or 100 ampoules per plastic ampoule tray.

Supplier
Steril-Gene Life Sciences (P) Ltd
No.15, Gopalakrishna Road
T. Nagar, Chennai-600 017
India

Manufacturer
Steril-Gene Life Sciences (P) Ltd
45, Mangalam Main Road
Mangalam Village
Villianur Commune
Puducherry- 605110
India

For any information about this medicine, contact the supplier:

This leaflet was last revised in February 2020.
Section 6 updated in May 2021.

Detailed information on this medicine is available on the World Health Organization (WHO) web site: https://extranet.who.int/prequal/.

The following information is intended for healthcare providers only.

Method of administration for each indication:

Oxytocin should not be started for 6 hours following the administration of vaginal prostaglandins. Oxytocin should be administered as an intravenous drip infusion or, preferably, by means of a variable-speed infusion pump. For drip infusion it is recommended that 5 units of oxytocin is added to 500 ml of a physiological electrolyte solution (such as sodium chloride 0.9%). 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.
The initial infusion rate should be set at 1 to 4 milliunits/minute (2 to 8 drops/minute). It may be gradually increased at intervals of at least 20 minutes and increments of not more than 1– 2 milliunits/minute, until a contraction pattern similar to that of normal labour is established.
In pregnancy near term this can often be achieved by infusing at a rate of less than 10 milliunits/minute (20 drops/minute), and the recommended maximum rate is 20 milliunits/minute (40 drops/minute). In the unusual event that higher rates are required, as may occur in the management of fetal 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 units in 500 ml.

When using a motor-driven infusion pump which delivers smaller volumes than those 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 fetal 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 or fetal 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 units, 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 milliunits/minute.

Incomplete, inevitable or missed abortion

The usual dose is 5 units by intravenous infusion (5 units diluted in physiological electrolyte solution and administered as an intravenous drip infusion or preferably, by means of a variable-speed infusion pump over 5 minutes), if necessary followed by intravenous infusion at a rate of 20 to 40 milliunits/minute.

Caesarean section

The ususal dose is 5 units by intravenous infusion (5 units diluted in physiological electrolyte solution and administered as an intravenous drip infusion or, preferably, by means of a variable-speed infusion pump over 5 minutes) immediately after delivery.

Prevention of postpartum uterine haemorrhage

The usual dose is 10 units by intramuscular injection. Alternatively, 5 units can be given by intravenous infusion (5 units diluted in physiological electrolyte solution and administered as an intravenous drip infusion or, preferably, by means of a variable-speed infusion pump over 5 minutes) 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 afterwards.

Treatment of postpartum uterine haemorrhage

The usual dose is 10 units by intramuscular injection. Alternatively, 5 units can be given by intravenous infusion (5 units diluted in physiological electrolyte solution and given as an intravenous drip infusion or, preferably, by means of a variable-speed infusion pump over 5 minutes), followed in severe cases by intravenous infusion of a solution containing oxytocin 5 to 20 units in 500 ml of an electrolyte-containing diluent, run at the rate necessary to control uterine atony.

Note

Oxytocin should not be infused through 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.