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.[*]
The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

[*] https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[RH050 trade name] †
Oxytocin

If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.

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 is for you only. Do not pass it on to others. It may harm them, even if their illness seems 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 [RH050 trade name] is and what it is used for
2. What you need to know before you take [RH050 trade name]
3. How to take [RH050 trade name]
4. Possible side effects
5. How to store [RH050 trade name]
6. Contents of the pack and other information

1. What [RH050 trade name] is and what it is used for

[RH050 trade name] contains a manufactured form of oxytocin (a natural hormone). It makes the muscles of the womb contract.

[RH050 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 [RH050 trade name]

You must not receive [RH050 trade name]:

- If you are allergic to oxytocin or any of the other ingredients of this medicine (listed in section 6)
- If your health care provider thinks that to start or increase contractions of the womb would be unsuitable, for example:
    - if contractions of the womb are unusually strong
    - if there is a blockage that could prevent delivery
    - if your baby may not be receiving enough oxygen
- Where labour or delivery through the birth canal is not advisable, for example, if:
    - your baby's head is too large to fit through the birth canal
    - your baby is not in the right position in the birth canal

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

- the placenta lies near or over the neck of your womb
- your baby separates from the womb before the baby is born
- there are loops of umbilical cord between the baby and the neck of the womb either before or after your waters break
- your womb is over-stretched 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
- you have had at least five pregnancies in the past or if your womb is scarred by previous caesarean section or other surgery

- If you have just been given medicines called prostaglandins (used to bring on labour or treat stomach ulcers). [RH050 trade name] should be used at least 6 hours after vaginal prostaglandins as the combined effects of both medicines may be too strong.

[RH050 trade name] should not be used for prolonged periods if:

- the treatment does not increase your contractions
- 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

Talk to your health care provider before you receive [RH050 trade name] if:

- you are prone to chest pain because of problems with your heart or blood circulation
- you have an irregular heartbeat (‘long QT syndrome’) or problems with your heart rhythm, or if you are taking medicines that affect the heart rhythm (see under ‘Other medicines and [RH050 trade name], below’)
- you have previously had a caesarean 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
- your health care provider has told you that normal delivery may be difficult because your pelvis is too small
- you have kidney problems, as oxytocin may cause build-up of water in your body
- you have had complications during your pregnancy
- you are more than 40 weeks pregnant

Your health care provider will look out for any complications that can arise from using this medicine.

When this medicine is given into a vein, your health care provider will make sure it is given at the proper speed. Tell your health care provider if you feel faint or dizzy, your heartbeat gets fast, or you feel hot and flushed all over. This can happen if the medicine is given too fast.

When [RH050 trade name] is given to induce and enhance labour, your health care provider will adjust the infusion speed so that you have contractions similar to normal labour. If the speed is too high the contractions may be too strong and too long, which may cause the womb to tear with serious complications for you and your baby.

High doses of [RH050 trade name] may force amniotic fluid from your womb into your blood. This is known as amniotic fluid embolism.

Tell your health care provider if, after your baby is born, you bleed too easily or have anaemia because these may be signs of a rare side effect called disseminated intravascular coagulation.

Large doses of [RH050 trade name] over a long period whilst drinking or receiving large amount of fluid may cause a build-up of water in your body, 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 health care provider before you receive [RH050 trade name].

Latex allergy

The active substance in [RH050 trade name] can cause a severe allergic reaction (anaphylaxis) in patients with latex (rubber) allergy. Tell your health care provider if you are allergic to latex.

Children and adolescents

[RH050 trade name] is not intended for use in children or adolescents.

Other medications and [RH050 trade name]

Tell your health care provider if you are taking or have recently taken any of the following medicines as they may interfere with [RH050 trade name]:

- Prostaglandins (used to start labour or to treat stomach ulcers) and similar medicines 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 breathe 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
- Medicines that can increase your blood pressure or raise your heartbeat (which are sometimes also included in anaesthetic medicines applied to your body to relieve pain). Using these medicines at the same time as [RH050 trade name] may increase blood pressure.

Tell your health care provider if you are taking or have recently taken or might take any other medicines.

[RH050 trade name] with food and drink

Your health care provider may tell you 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, [RH050 trade name] is not expected to harm your baby when used correctly.

Oxytocin may be present 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

[RH050 trade name] can start labour. Women with uterine contractions should not drive or use machines.

3. How [RH050 trade name] is given

[RH050 trade name] is given to you by a health care provider in a hospital.

Your health care provider will decide when and how to treat you with [RH050 trade name]. If you think that the effect of [RH050 trade name] is too strong or too weak, tell your health care provider.

While you are receiving [RH050 trade name], you and your baby will be closely monitored.

[RH050 trade name] is usually given as an infusion (drip) into one of your veins but it can also be given by injection into your muscles.

The dose you get depends on what the medicine is being used for.

To start or help contractions during labour

The rate of infusion will start at 10 drops per minute. This may be gradually increased to a maximum rate of 60 drops per minute. If necessary, your health care provider may change the infusion bag to increase the amount of medicine in the infusion bag. The infusion rate can often be reduced once you have a good pattern of contractions of about 3 to 4 contractions every 10 minutes.

If you do not reach a good pattern of contractions with the medicine, you may need to have a caesarean section to deliver your baby safely.

Miscarriage

The dose is 5 units by infusion into a vein. Your health care provider may continue the infusion if you need more medicine.

Caesarean section

The dose is 5 units by infusion into a vein immediately after delivery of your baby.

Prevention of bleeding after delivery

The dose is 10 units by injection either into your vein or into a muscle. Your health care provider may give you the medicine into your vein if you are already being given other medicines in this way.

Treatment of bleeding after delivery

If you already have a drip running, you may be given 10 to 40 units in the drip. Your health care provider will adjust the speed of the drip depending on your contractions. In some cases, you may be given the medicine by injection into your muscle.

If you receive more [RH050 trade name] than you should

As this medicine is given to you by your health care provider, 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 health care provider immediately. Show any left-over medicines or the empty packet to the doctor.

An overdose of [RH050 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 have any further questions on the use of this medicine, ask your health care provider.

4. Possible side effects

Possible side effects

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

Effects in the mother

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

- Headache
- Fast or slow heartbeat
- Feeling sick (nausea) or being sick (vomiting)

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

- An irregular heartbeat

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

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

The following side effects can also occur, but it is not known how common they are:

- Chest pain (angina)
- Irregular heartbeat (QTc prolongation seen on electrocardiogram)
- Low blood pressure
- Haemorrhage (bleeding)
- Excessive contractions
- Excessive or continuous contractions
- Tearing of the womb
- Rapid swelling under the skin in areas such as the face, throat, arms and legs
- Fluid retention (water build-up). 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

The following side effects can also occur, but it is not known how common they are:

- Low blood salt levels
- Excessive contractions in the womb may cause shortage of oxygen, suffocation and death

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [RH050 trade name]

The hospital pharmacy will store this medicine in a refrigerator between 2 to 8°C and in the original package to protect it from light.

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 after {EXP}.The expiry date refers to the last day of that month.

This medicine must not be used if description of the visible signs of deterioration.

Do not throw away any medicines in wastewater or household waste. 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 [RH050 trade name] contains

- The active ingredient is oxytocin.
- The other ingredients of [RH050 trade name] are chlorobutanol hemihydrate, glacial acetic acid, sodium acetate, ethanol, sodium chloride

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

What [RH050 trade name] looks like and contents of the pack

[RH050 trade name] is a clear, colourless, sterile liquid which comes in a 1ml (millilitre) clear glass ampoule.

Each [RH050 trade name] ampoule contains oxytocin 10 International Units

Supplier and Manufacturer

Supplier

PT SANBE FARMA
JL Taman Sari 10
Bandung, Indonesia
Tel: + 62 22 4207725
Fax: + 62 22 4238476
E-mail: export.sanbefarma@gmail.com

Manufacturer

PT. SANBE FARMA Unit 3
Sterile Preparation Plant
Jl. Industri Cimareme No. 8
Padalarang, Bandung
Indonesia
Tel: 62-22-6867966
Fax: 62-22-6867969
E-mail: unit3.sanbefarma@gmail.com

For any information about this medicine, contact the local representative of the supplier.

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Detailed information on this medicine is available on the World Health Organization (WHO) website: https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products

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The following information is intended for health care providers only:

[RH050 trade name] solution for infusion

oxytocin 10 units/ml

Method of administration for each indication:

Oxytocin should not be started for 6 hours following the administration of vaginal prostaglandins. [RH050 trade name] 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 [RH050 trade name] 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 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) 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 [RH050 trade name] 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

[RH050 trade name] should not be infused through the same apparatus as blood or plasma, because the peptide linkages are rapidly inactivated by oxytocin-inactivating enzymes. [RH050 trade name] is incompatible with solutions containing sodium metabisulphite as a stabiliser.

Storage

Store between 2º and 8ºC.