PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Santocyn[1] 10 units/ml for injection

Oxytocin

Read all of this leaf let carefully before you receive this medicine because it contains important information for you

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your healthcare provider
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, tell your healthcare provider.

What is in this leaflet

1. What Santocyn is and what it is used for

Santocyn contains the active substance oxytocin. It belongs to a group of medicines called oxytocics which make the muscles of the uterus (womb) contract.

Oxytocin is used:

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

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

You must not receive Santocyn if:

- you are allergic (hypersensitive) to oxytocin or to any of the other ingredients of this medicine (listed in section 6)
- your healthcare provider thinks that to start or increase contractions of the womb would be unsuitable for you.

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Take special care with Santocyn

Oxytocin should only be administered by a healthcare professional in a hospital setting.

Santocyn should be given by infusion (drip) into your vein. It can be given by rapid injection into a vein but this may suddenly lower your blood pressure, cause a brief sensation of heat (often over the entire body), and speed up your heart beat.

Before you are given oxytocin, tell your healthcare provider if:

- you are prone to chest pain due to heart or circulation problems
- you have irregular heart beat ('long QT syndrome') or you are taking medicines can cause irregular heart beat
- you have had a previous caesarean section
- you have raised blood pressure or heart problems
- 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,
- you have had complications during your pregnancy
- you are over age 35 years
- your pregnancy has lasted longer than 40 weeks

Taking other medicines

Tell your healthcare provider if you are taking or have recently taken any of the following medicines as they may interfere with oxytocin:

- prostaglandins (used to start labour or to treat stomach ulcers) as the effects of both drugs may be increased
- medicines that can cause an irregular heartbeat, as oxytocin may increase this effect
- anaesthetics (used to put you to sleep during surgery) e.g. cyclopropane or halothane, as their use with oxytocin may cause problems with your heartbeat

Tell your healthcare provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Santocyn with food and drink

Your healthcare provider may ask you to keep the amount of liquids you drink to a minimum to prevent build-up of fluid in your body.

Pregnancy and breast-feeding

It is not expected that oxytocin would be a risk to your baby when used correctly.

Driving and using machines

Taking oxytocin can start labour. Women with contractions should not drive or use machines.

3. How Santocyn is given to you

Your healthcare provider will decide when and how to treat you with Santocyn. While you are receiving it, both you and your baby will be closely monitored. Santocyn can be given by

injection into a muscle or a vein, or it is diluted before use and given as an intravenous infusion (drip) into one of your veins. An electronic pump may be used to give the medicine into the vein.

Your healthcare provider may adjust the dose and the speed of your drip to control the medicine's effects.

4. Possible side effects

Like all medicines, Santocyn can cause side effects, although not everyone gets them. If you get any side effects, including any that are not listed in this leaflet, talk to your healthcare provider

A serious allergic reaction can occur rarely. Tell your healthcare provider straightaway if you:

- have swelling of your face, lips, tongue, throat or other parts of the body
- have breathing difficulty
- have weak or fast pulse
- feel dizzy or lightheaded
- feel faint
- have cold and clammy skin
- have nausea (feel sick)

Common side effects (that affect more than 1 in 100 patients) of Santocyn include:

- headache
- fast or slow heartbeat
- nausea and vomiting

Other side effects in the mother are:

- bleeding
- chest pain (angina)
- irregular heartbeat
- excessive or continuous contractions or spasm of the womb
- tearing of the womb
- fluid retention. Symptoms may include headache, loss of appetite, feeling or being sick, stomach pain, sluggishness, drowsiness, unconsciousness, low levels of sodium or potassium in the blood, fits
- low blood salt levels
- fluid build-up in the lungs
- brief sensation of heat often over the whole body
- abnormal clotting, bleeding and anaemia

Possible side effects in the baby are reduced levels of some salts in the blood, shortage of oxygen, suffocation, death

5. How Santocyn is stored

Keep out of the reach and sight of children.

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. It should not be used after the expiry date on the pack.

6. Contents of the pack and other information

The active ingredient in this medicine is oxytocin.

The other ingredients are chlorobutanol hemihydrate, glacial acetic acid, sodium acetate, ethanol, sodium chloride

What Santocyn looks like and the contents of the pack:

Santocyn is a clear, colourless, sterile liquid which comes in a 1ml (millilitre) clear glass ampoule.

Each Santocyn ampoule contains oxytocin 10 International Units

This leaflet was last approved in January 2018

Detailed information on this product is available on the website of the WHO Prequalification program https://extranet.who.int/prequal

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The following information is intended for healthcare providers only

Santocyn 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. Santocyn 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 Santocyn 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 Santocyn 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

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

Storage

Store between 2º and 8ºC.