
PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

SANTOCYN® 10 IU/ml Injection

Oxytocin

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Santocyn is and what it is used for
2. Before you use Santocyn
3. How to use Santocyn
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1. WHAT SANTOCYN IS AND WHAT IT IS USED FOR

Santocyn contains Oxytocin, which have simulation effect on the smooth musculature of the uterus, particularly towards the end of pregnancy, during labour and after delivery. It may be used:

- To start or help contractions during labour for medical reasons.
- To prevent and control of bleeding after delivery.
- During a caesarean section.
- To manage of incomplete, missed or inevitable abortion.

2. BEFORE YOU USE SANTOCYN

The induction of labour by means of oxytocin should be attempted only when strictly necessary for medical reasons. Administration should only be under hospital supervision and qualified medical supervision.

Do not use Santocyn:

- If spontaneous labour or vaginal delivery is inadvisable.
- If contractions of the womb are unusually strong.
- If you are allergic (hypersensitive) to Oxytocin or any of the other ingredients of Santocyn.
- Santocyn should not be used for prolonged periods in patients who have a condition known as severe pre-eclampsictoxaemia (high blood pressure, protein in the urine, swelling) or severe cardiovascular disorders (problems with their heart or circulation).
- When Oxytocin is used for prevention or treatment of uterine haemorrhage, rapid intravenous injection should be avoided, as it may cause an acute short-lasting drop in blood pressure.

Take special care with Santocyn

Before you receive Santocyn tells your doctor if:

- you have had a previous caesarean section
- you have been given any other medicines to induce labour (e.g. prostaglandins) in the past 6 hours
- 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 doctor that normal delivery may be difficult for you due to the small size of your pelvis.
- your kidneys do not work properly (renal impairment).
- there is foetal death in your womb or in the presence of meconium-stained amniotic fluid, tumultuous labour must be avoided, as it may cause amniotic fluid embolism.

Using other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- When Santocyn is given with drugs known as prostaglandins the effects of each drug may be increased.
- Some anaesthetics (drugs which make you lose sensation and/or consciousness temporarily) given by inhalation may reduce the effect of Santocyn.
- When given during or after epidural, Santocyn may increase the effects of some drugs given to constrict the blood vessels.

Using Santocyn with food and drink

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

Pregnancy and breast-feeding

Ask your doctor for advice before taking any medicine.

Driving and using machines

Do not drive or use any tools or machines as Santocyn induces labour.

Important information about some of the ingredients of Santocyn

Santocyn contains small amounts of ethanol (alcohol).

3. HOW TO USE SANTOCYN

Always use Santocyn exactly as your doctor has told you. You should check with your doctor if you are not sure.

Santocyn injection is usually diluted before use and given as an intravenous infusion (drip) into one of your veins. The dose of Santocyn used varies depending on the reason for its use. When used to start or help contractions during labour the dose are normally expressed as the dose given each minute (mUnit/min or drops per min). The dose is carefully controlled and adjusted according to response.

The usual dose is different in the following circumstances:

- **To start or help contractions during labour:**
Santocyn should be administered as an intravenous infusion or preferably, by means of a variable-speed infusion pump. The initial infusion rate should be set at 1- 4 mU/min (2-8 drops/min). It may be gradually increased at intervals not shorter than 20 min.
Your contractions and your baby's heart rate will be carefully monitored while you are receiving Santocyn.
- **Caesarean section:**
The dose is 5 IU by slow injection into a vein immediately after delivery of your baby.
- **Prevention of bleeding after delivery:**
The dose is 5 IU slowly intravenous or 5-10 IU intramuscular after delivery of the placenta. 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 thereafter.

- **Treatment of bleeding after delivery:**
The dose is 5 IU slowly intravenous or 5-10 IU intramuscular, followed in severe cases by intravenous infusion 5-20 IU of Oxytocin in 500 ml of a non-hydrating diluent, run at the rate necessary to control uterine atony.
- **Incomplete, inevitable, or missed abortion:**
The dose is 5 IU slowly intravenous or 5-10 IU intramuscular, if necessary followed by intravenous infusion at a rate of 20-40 mU/min or higher.

Whenever high doses of Oxytocin are administered over a long time, an electrolyte-containing diluent must be used (not dextrose), the volume of infused fluid should be kept low (by infusing Oxytocin at a higher concentration than recommended for the induction or enhancement of labour at term), fluid intake by mouth must be restricted.

If you use more Santocyn than you should

A doctor or a nurse will usually give you this medicine. If you think you may have received too much medicine, please tell your doctor or nurse at once.

An overdose of Santocyn 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 forget to use Santocyn

A doctor or nurse will usually give you this medicine. If you think you have missed a dose, please tell your doctor.

If you stop using Santocyn

A doctor or a nurse will usually give you this medicine and they will discontinue when appropriate. If you have any further questions on the use of this product, ask your doctor or health care provider.

4. POSSIBLE SIDE EFFECTS

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

- Administration of Oxytocin in high doses may cause very strong contractions of the womb, tearing of the womb and tissue damage. This could result in distress, suffocation or death of the baby.
- If high doses of Santocyn are given with large volumes of certain fluids the condition of water intoxication associated with dilution of the electrolytes in the bloodstream of both the mother and the foetus, may occur. When Santocyn is given with large amount of fluid it may lead to an acute pulmonary oedema (a situation when fluid is accumulated in the lungs).
- Rapid administration of Santocyn as a bolus injection (a high starting dose) may result in an acute, short-lasting drop in blood pressure accompanied by flushing and rapid heartbeat. This may lead to the chest pain or discomfort occurring when an area of the heart muscle doesn't get enough oxygen-rich blood (myocardial ischemia), particularly in patients with preexisting cardiovascular disease. Rapid bolus injections of the drug may also affect the heart muscle activity displayed by ECG.
- Some patients sensitive to Oxytocin may experience spasm of the muscles of the womb at what would normally be considered to be low doses.
- Symptoms may include:
 - nausea
 - vomiting
 - cardiac arrhythmias
 - skin rashes

- shortness of breath
- hypotension
- shock

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE SANTOCYN

Keep out of the reach and sight of children.

Store the ampoules refrigerated (2 - 8°C) in the original cartons protected from light.

Do not freeze.

Do not use Santocyn after the expiry date which is stated on the carton and vial label after EXP. The expiry date refers to the last day of that month

Single use only.

Discard unused portion in accordance with local requirements.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Santocyn contains

- The active substance is oxytocin. Each 1 ml ampoule contains 10IU/mL of oxytocin.
- The other ingredients are chlorbutanol hemihydrate, glacial acetic acid, sodium acetate anhydrate, ethyl alcohol, sodium chloride and water for injection.

What Santocyn looks like and contents of the pack

Solution for injection.

Clear glass ampoule containing 1 mL of a clear colourless, sterile solution.

Santocyn is available in packs containing 10 ampoules.

Supplier and Manufacturer

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This leaflet was last approved in

02/2021

Detailed information on this medicine is available on the WHO Prequalification web site:
<http://www.who.int/prequal/>