**Syntocinon 5 IU/ml, concentrate for solution for infusion and solution for injection**

oxytocin

**What is syntocinon and what is it used for?**Syntocinon belongs to a group of medicines called oxytocics. Syntocinon contains synthetic oxytocin, which is identical to the natural hormone oxytocin. Oxytocin causes rhythmic contractions of the uterus. It also stimulates milk ejection from the mammary gland.

Syntocinon is given as an intravenous infusion and can be used to:

* Induce labor contractions.
* Assist during and immediately after delivery to facilitate labor.
* Prevent or control bleeding after delivery.

If you have any questions about how Syntocinon works or why this medicine has been prescribed to you, ask your doctor.

**When should you not use this medicine or use it with extra caution?**

**When should you not use this medicine?**

* If you are allergic to any of the substances in this medicine.
* If your doctor believes that inducing or enhancing labor would be unsuitable for you, for example:
* When contractions of your uterus are unusually strong.
* When there is an obstruction that could hinder delivery or when delivery or vaginal birth is not advisable, as in the following cases:
* If the baby is too large in proportion to your pelvis.
* If the unborn child is not in the head-down position.
* If the placenta is blocking the cervix.
* In cases of premature placental abruption.
* If the blood vessels in the placenta or umbilical cord of the unborn child are located in front of the birth canal.
* If you are pregnant with multiple babies.
* If there is excessive amniotic fluid in the uterus.
* If you have had more than 4 full-term pregnancies.

When you have previously had a classical cesarean section or surgery on your uterus.

When the unborn child has oxygen deficiency or disturbed heart rate ("fetal distress").

When vaginal prostaglandins (certain medications to induce labor) have been administered to you less than 6 hours ago, and when a vaginal delivery system with prostaglandins has been removed less than 30 minutes ago (see "Are you using any other medications?").

**When should you take extra caution with this medicine?**

Contact your doctor or nurse before using this medication. The induction of labor using oxytocin should only be attempted if strictly necessary for medical reasons. Administration should only take place in the hospital and under qualified medical supervision.

Syntocinon should not be administered as a rapid injection into a blood vessel (bolus injection). This can cause a sudden, transient drop in blood pressure .

Syntocinon should not be administered for a prolonged period of time:

* When you have weak contractions that do not respond to Syntocinon.
* When you have pre-eclampsia (characterized by high blood pressure, protein in the urine, and swelling).
* When you have severe heart and vascular diseases.
* Your doctor or nurse will exercise particular caution when treating you with Syntocinon:
* If delivery could be complicated due to the baby being too large in proportion to your pelvis.
* When you have mild to moderate high blood pressure.
* When you have a certain heart and vascular disease that could reduce blood flow to the heart.
* When you have a certain heart condition (long QT syndrome) in which severe heart rhythm disorders can occur spontaneously, or when you are taking medications that can cause rhythm disorders.
* If you have previously had a cesarean section.
* If you are 35 years or older, have experienced complications during pregnancy, or if the gestation period has exceeded 40 weeks. The risk of a certain severe blood clotting disorder (disseminated intravascular coagulation) is increased in such cases.
* If your kidneys are not functioning properly.
* Latex Allergy
* The active substance in Syntocinon can cause a severe allergic reaction (anaphylaxis) in patients with a latex allergy. Inform your doctor if you are allergic to latex.

**Are you taking any other medications?**

If you are taking or have recently taken any other medications, including those obtained without a prescription, medications obtained abroad, natural products, strong vitamins and minerals, as well as dietary supplements, inform your doctor or pharmacist.

**The following medications can affect the effectiveness of Syntocinon or be affected by Syntocinon:**

Prostaglandins and similar substances (used to induce labor) can enhance the stimulating effect of oxytocin and vice versa.

Certain inhalation anesthetics administered during anesthesia (inhaled anesthetics such as cyclopropane, halothane, sevoflurane, desflurane) can reduce the effect of Syntocinon on the uterus.

Syntocinon can cause heart rhythm disorders, and simultaneous use with other medications that can also cause heart rhythm disorders is therefore not recommended.

When oxytocin is administered during or after local anesthesia (epidural), it can enhance the blood pressure-increasing effect of the anesthetic.

Concurrent administration of oxytocin can enhance the blood pressure-increasing effect of ergot alkaloids (certain group of medications used for the treatment of migraine).

**Pregnancy and breastfeeding**

**Pregnancy:** Syntocinon can be used for the indicated indications, but with great caution and only in combination with monitoring of uterine activity and the fetal heart rate.

**Breastfeeding:** Oxytocin (the active ingredient in Syntocinon) may be present in small amounts in breast milk. However, no harmful effects have been found in infants.

**Driving and using machinery:** Syntocinon can induce contractions. Therefore, driving a vehicle or operating machinery is not recommended. Syntocinon contains ethanol (alcohol) and sodium This medicine contains 5 mg of alcohol (ethanol) per dosage unit. The amount per dose in this medicine is equivalent to 0.12 ml of beer or 0.05 ml of wine. There is a small amount of alcohol in this medicine. It is so little that you will not notice it. This medicine contains less than 1 mmol of sodium (23 mg) per dose unit, which means it is essentially 'sodium-free.'

**How to use this medicine?**Follow the advice of your doctor closely when using Syntocinon. If you are unsure about the correct use, consult your doctor or pharmacist.

Syntocinon is usually diluted before use and administered as an infusion into your veins. Sometimes, Syntocinon is administered undiluted into a muscle or vein.

The dose to be administered depends on the reason for use.

Your doctor will determine how, how much, and for how long Syntocinon will be administered to you.

The standard dose is 5 IU via an intravenous infusion.

For the treatment of severe bleeding after childbirth, Syntocinon may also be administered into a muscle at a dose of 5-10 IU, and in severe cases followed by 5-20 IU via intravenous infusion.

Do you have any other questions about the use of this medication? Contact your doctor or pharmacist.

**Impaired kidney function:** Oxytocin can interfere with urine formation. This can cause the body to retain water when the sodium level in the blood is too low. Therefore, the administration of oxytocin is not advised in patients with severely impaired kidney function.

**Elderly (65 years and older)** There is no information about the use in elderly patients. Syntocinon is not intended for use in the elderly.

**Use in children and adolescents under 18 years of age:** There is no information about the use in children.

If too much of this medication has been administered, Usually, a doctor or nurse will administer this medication, making it unlikely that you will receive an overdose. If you think you have received too much of this medicine, immediately contact your doctor or nurse.

**Symptoms of an overdose:** In addition to the symptoms mentioned in the sections "When to exercise caution with this medicine?" and "Possible side effects include premature placental detachment and amniotic fluid embolism (where amniotic fluid enters the bloodstream) reported with uterine overstimulation. Amniotic fluid embolism can cause bluish discoloration and respiratory difficulties, decreased level of consciousness, or confusion."

**Treatment:** When signs or symptoms of overdose occur during continuous administration of Syntocinon in a blood vessel, the administration should be immediately stopped, and oxygen should be given to the mother.

**Possible Side Effects**Like any medicine, this medicine can also have side effects. Not everyone experiences them.

Some of these side effects can be serious and require medical treatment. Immediately inform a doctor if you experience any of these serious side effects.

Under rare circumstances (may occur in less than 1 in 1,000 patients), a severe allergic reaction, accompanied by shortness of breath, low blood pressure, or shock (severe drop in blood pressure, pallor, restlessness, weak rapid pulse, clammy skin, decreased level of consciousness) can occur.

**Other side effects that may occur in the mother are:**

**Common side effects (may occur in less than 1 in 10 patients):** Headache, Increased heart rate, Decreased heart rate, Nausea, Vomiting

**Uncommon side effects (may occur in less than 1 in 100 patients);** Cardiac arrhythmias

**Rare side effects (may occur in less than 1 in 1,000 patients):** Skin rash

Side effects with unknown frequency (cannot be estimated from the available data)

Severe coagulation disorder (disseminated intravascular coagulation)

Water intoxication due to the use of very high doses of oxytocin for extended periods in combination with large amounts of certain fluids (signs include headache, nausea, vomiting, drowsiness, lack of energy, abdominal pain (other than contractions))

* Low sodium levels in the blood; fluid retention
* Heart attack; reduced blood flow to the heart; certain cardiac arrhythmias (prolonged QTc interval, accelerated heart rate)
* Low blood pressure; flushing
* Pulmonary edema (fluid accumulation in the lungs)
* Spasms of the uterine muscles; uterine rupture; overstimulation of uterine contractions;
* Swelling of the skin and tissues beneath the skin or of the mucous membranes (angioedema).

The following side effects may occur in the child:

* Side effects with unknown frequency (cannot be estimated from the available data)
* Low sodium levels in the blood
* Jaundice
* Lack of oxygen
* Suffocation due to insufficient oxygen or excessive carbon dioxide in the blood
* Death.

If you experience any side effects, contact your doctor or nurse. This also applies to side effects not listed in this leaflet. You can also report side effects to the Netherlands Pharmacovigilance Centre Lareb (www.lareb.nl). By reporting side effects, you help us gather more information about the safety of this medicine.

**How to store this medicine?**

* Keep out of sight and reach of children.
* Store in the refrigerator (2°C - 8°C).
* Once outside the refrigerator, the ampoules are still usable for up to 3 months below 30°C.
* Do not use this medicine after the expiry date stated on the label and box (EXP). The expiry date is indicated as a month and a year. The last day of that month is the expiry date.
* Do not dispose of medicines in wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. When you dispose of medicines correctly, they are destroyed in an environmentally friendly manner and do not enter the environment.