PATIENT INFORMATION LEAFLET

Syntocinon® 5 IU/ml and 10 IU/ml Concentrate for solution for infusion
oxytocin

Read all of this leaflet 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 doctor, midwife or pharmacist.
- If you get any side effects, talk to your doctor, midwife or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Syntocinon is and what it is used for

Syntocinon 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.

Syntocinon 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 receive Syntocinon

You must not receive Syntocinon:
- if you are allergic to oxytocin or any of the ingredients of this medicine (listed in section 6)
- if your doctor 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 the placenta lies near or over the neck of your womb
    - if your baby lacks oxygen due to blood vessels running across the neck of your womb
    - if the 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 caesarean section or other surgery

• if you have been given medicines called prostaglandins (used to bring on labour or treat stomach ulcers). Syntocinon should not be used for 6 hours after vaginal prostaglandins as the effects of both medicines may be increased

Syntocinon should not be used for prolonged periods if:
• your contractions do not increase with the treatment
• you have a condition known as severe pre-eclampsia (high blood pressure, protein in the urine and swelling)
• you have severe problems with your heart or blood circulation.

Warnings and precautions
Syntocinon should only be administered by a healthcare professional in a hospital setting.

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

Before you receive Syntocinon tell your doctor or midwife if:
• you are prone to chest pain due to pre-existing heart and/or circulation problems
• you have a known irregular heart beat (‘ long QT syndrome’) or related symptoms, or are taking medicines known to cause the syndrome (see section ‘ Other medicines and Syntocinon’)
• you have had a previous 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
• you have been told by a doctor or midwife that normal delivery may be difficult for you due to the small size of your pelvis
• you have kidney problems, as Syntocinon can cause water retention
• you have had complications during your pregnancy
• you are more than 40 weeks pregnant.

When Syntocinon is given to induce and enhance labour, the infusion rate should be set to maintain a contraction pattern similar to normal labour and adjusted 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.

Syntocinon may rarely cause disseminated intravascular coagulation which causes symptoms including abnormal blood clotting, bleeding and anaemia.

High doses of Syntocinon may force amniotic fluid from your womb into your blood. This is known as amniotic fluid embolism.

Large doses of Syntocinon 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 applies to you, or if you are not sure, speak to your doctor or midwife before you

receive Syntocinon.

Latex allergy
The active substance in Syntocinon might cause a severe allergic reaction (anaphylaxis) in patients with latex allergy. Please tell your doctor if you know you are allergic to latex.

Other medicines and Syntocinon
Tell your doctor or midwife if you are taking or have recently taken any of the following medicines as they may interfere with Syntocinon:
- 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 Syntocinon 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
- anaesthetic medicines for local or regional pain relief, in particular an epidural for pain relief during labour. Syntocinon may increase the blood vessel narrowing effect of these medicines and cause an increase in blood pressure.

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

Syntocinon with food and drink
You may be told to keep the amount of fluids you drink to a minimum.

Pregnancy and breast-feeding
Based on wide experience of use and the nature of this medicine, it is not expected that Syntocinon would be a risk to your baby when used correctly. Syntocinon 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.

Driving and using machines
Syntocinon can start labour. Women with contractions should not drive or use machines.

Information on sodium content
This medicine contains less than 1 mmol sodium (23 mg) per 1ml, that is to say essentially 'sodium-free'.

3. How Syntocinon is given to you

Your doctor or midwife will decide when and how to treat you with Syntocinon. If you think that the effect of Syntocinon is too strong or too weak, tell your doctor or midwife. While you are receiving Syntocinon, both you and your baby will be closely monitored.

Syntocinon 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 3-4 contractions every 10 minutes.

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

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

Prevention of bleeding after delivery
The dose is 5 IU by infusion into a vein after delivery of the placenta.

Treatment of bleeding after delivery
The dose is 5 IU by infusion into a vein. In some cases this may be followed by a drip containing 5 to 20 IU of oxytocin.

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

Children and adolescents
There is no information on use in children (2-11 years) or adolescents (12-17 years). Syntocinon is not intended for use in children or adolescents.

Patients with kidney disease
There is no information on use in patients with kidney disease.
However, you should tell your doctor if you suffer from kidney problems (see section 2 ‘ Warnings and precautions’)

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

What to do if you receive more Syntocinon 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 Syntocinon 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.

What to do if you miss a dose
As a doctor or midwife 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 doctor or midwife.

4. Possible side effects

Like all medicines, Syntocinon can cause side effects, although not everyone gets them. Your doctor may consider it necessary to treat the side effects of Syntocinon with other medicines.
Some side effects could be serious. If any of the following occur, tell your doctor straight away:
The following side effect may affect between 1 and 10 in every 10,000 patients:

- a severe allergic (anaphylactic/anaphylactoid) reaction with difficulty in breathing, dizziness and lightheadedness, feeling faint, nausea, cold and clammy skin or a fast or weak pulse
- Swelling of the face, lips, tongue, throat, and/or extremities (possible signs of angioedema)

The following side effects have been reported in Syntocinon

Common side effects (more than 1 in 100 patients) of Syntocinon include:
- feeling or being sick
- headache
- fast or slow heartbeat

Uncommon side effects (more than 1 in 1,000 patients) of Syntocinon include:
- an irregular heartbeat.

Rare side effects (more than 1 in 10,000 patients) of Syntocinon include:
- skin rashes

Other side effects
Effects in the mother:
- haemorrhage (bleeding)
- chest pain (angina)
- irregular heartbeat
- 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 often over the whole body
- abnormal clotting, bleeding and anaemia
- spasm of the muscles of the womb

Effects in the baby:
Excessive contractions may cause low blood salt levels, shortage of oxygen, suffocation and death.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or midwife. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom	Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Syntocinon

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

The hospital pharmacy will store this medicine in a refrigerator between 2º to 8°C and make sure that it is not used after the expiry date on the pack. The expiry date refers to the last day of that month.

Chemical and physical in-use stability has been demonstrated for 24 hours at room temperature (15 °C to 25 °C).
From a microbiological point of view, unless the method of opening/ reconstitution/ dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

If your doctor decides to stop your treatment, return any unused medicine to the pharmacist. Only keep it if your doctor tells you to.

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

6. Contents of the pack and other information

What Syntocinon contains
The active substance is oxytocin.
The other ingredients are sodium acetate tri-hydrate, sodium chloride, acetic acid and water for injections.

What Syntocinon looks like and contents of the pack
Syntocinon is a clear, colourless, sterile liquid which comes in a 1ml (millilitre) clear glass ampoule. Syntocinon comes in packs of five ampoules. Each Syntocinon ampoule contains either 5 IU (International Units) or 10 IU oxytocin.

Marketing Authorisation Holder
Mylan Products Ltd, 20 Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturer

Viatris UK Healthcare Limited, 20 Station Close, Potters Bar, EN6 1TL, United Kingdom

Haupt Pharma, 1 rue Comte de Sinard, Livron Sur Drome, 26250, France

The information in this leaflet applies only to Syntocinon. If you have any questions or you are not sure about anything, ask your doctor, midwife or a pharmacist.

This leaflet was last revised in May 2023

The following information is intended for medical or healthcare professionals only

Syntocinon® 5 IU/ml and 10 IU/ml Concentrate for solution for infusion
oxytocin

Method of administration for each indication:

Induction or enhancement of labour

Oxytocin should not be started for 6 hours following administration of vaginal prostaglandins. Syntocinon should be administered as an i.v. drip infusion or, preferably, by means of a variable-speed infusion pump. For drip infusion it is recommended that 5 IU of Syntocinon be added to 500ml 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 not shorter than 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 with an infusion 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 foetal 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 Syntocinon solution, e.g., 10 IU in 500ml.

When using a motor-driven infusion pump which delivers smaller volumes than those given 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 foetal 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 and/or foetal 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 IU, 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. **Continued overleaf**

Method of administration for each indication, continued:

Incomplete, inevitable or missed abortion

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

Caesarean section

5 IU by i.v. infusion (5 IU diluted in physiological electrolyte solution and administered as an i.v. 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 5 IU by i.v. infusion (5 IU diluted in physiological electrolyte solution and administered as an i.v. drip infusion or, preferably, by means of a variable-speed infusion pump over 5 minutes) after delivery of the placenta. In women given Syntocinon 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 postpartum uterine haemorrhage 5 IU by i.v. infusion (5 IU diluted in physiological electrolyte solution and administered as an i.v. drip infusion or, preferably, by means of a variable-speed infusion pump over 5 minutes), followed in severe cases by i.v. infusion of a solution containing 5 to 20 IU of oxytocin in 500ml of an electrolyte-containing diluent, run at the rate necessary to control uterine atony.

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

Storage - Store between 2º and 8ºC.

Syntocinon is a registered trademark.