SYNTOCINON®
(synthetic oxytocin)
5IU/1mL solution for infusion/injection
10IU/1mL solution for infusion/injection

What is in this leaflet
Read all of this leaflet carefully before you start taking this medicine.

This leaflet answers some common questions about SYNTOCINON. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given SYNTOCINON against the benefits your doctor expects it to provide. This medicine has been prescribed only for you. Do not give it to anybody else or use it for any other illnesses.

If any of the side effects affects you seriously, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.medsafe.govt.nz

Keep this leaflet. You may need to read it again.

What SYNTOCINON is
SYNTOCINON contains an active substance called oxytocin. It belongs to a group of medicines called oxytocics that stimulate contraction of the womb (uterus). It is identical with oxytocin, a natural hormone released by the pituitary gland.

The other ingredients are: Sodium acetate trihydrate, glacial acetic acid, chlorobutanol, ethanol 94%, water for injections.

What SYNTOCINON is used for
Before childbirth (antepartum)
• To bring on (induce) or enhance contractions of the womb (labour)
• To correct sluggish contractions (uterine inertia) during labour
• To manage incomplete, inevitable or missed miscarriage

After childbirth (postpartum)
• To help the womb contract during caesarean section, after delivery of the baby and placenta
• To prevent and treat bleeding if the womb fails to contract strongly enough after delivery of the baby and placenta

If you have any questions about how Syntocinon works or why it has been prescribed for you, ask your doctor.

How Syntocinon works
Syntocinon works by stimulating rhythmic contraction of the womb during labour and after delivery.
**Monitoring Syntocinon treatment**
During Syntocinon infusion, both you and your baby will be closely monitored to prevent complications so that the dosage can be adjusted to the individual response.

**Before receiving Syntocinon**
Follow all the doctor’s instructions carefully. They may differ from the general information contained in this leaflet.
It is important to tell your doctor if you have other medical problems or if you are taking other medicines.

**Syntocinon should not be used:**
- If you are allergic (hypersensitive) to oxytocin or to any of the ingredients of Syntocinon listed at the end of the leaflet under What Syntocinon is
- If your doctor thinks that inducing or enhancing contractions would be unsuitable for you. For example:
  - If you already have unusually strong (hypertonic) contractions
  - If your baby is short of oxygen (foetal distress) and delivery is not imminent
  - If your doctor advises against normal labour and/or vaginal delivery
- If there are maternal or foetal reasons for caesarean delivery. For example:
  - If your baby’s head is too large to fit through your pelvis (cephalopelvic disproportion)
  - If your baby is wrongly positioned in the birth canal (malpresentation)
  - If the placenta lies near or over the neck of your womb (placenta praevia)
  - If your baby lacks oxygen due to blood vessels running across the neck of your womb (vasa praevia)
  - If the placenta separates from the womb before the baby is born (abruption)
  - If there are one or more loops of umbilical cord between the baby and neck of the womb, before your waters break (cord presentation) or afterwards (cord prolapse).
  - If your womb is over-extended and more liable to burst (rupture), for example if you are carrying more than one baby (multiple pregnancy) or have too much water (amniotic fluid) in your womb (polyhydramnios)
  - If you have had five or more previous pregnancies (grand multiparity) or if your womb is scarred by a previous caesarean section or other surgery
  - If you have been given medicines called prostaglandins (used to bring on [induce] labour or treat stomach ulcers). Syntocinon should not be used for 6 hours after vaginal prostaglandins as the effects of both drugs may be increased

If any of these apply to you, you should not receive Syntocinon and you should consult your doctor.

If you think you may be allergic, ask your doctor for advice.

**Take special care with Syntocinon**
Syntocinon should be administered by a health care professional. It should be administered in a hospital setting where a qualified health care professional can monitor your contractions and handle emergencies appropriately.

Syntocinon should not be used for prolonged periods
- If it fails to increase your contractions (oxytocin-resistant uterine inertia)
- If you have high blood pressure, protein in the urine and swelling (pre-eclamptic toxaemia)
- If you have severe heart and/or circulation problems (severe cardiovascular disease)

Syntocinon should be used with caution
• If you are prone to chest pain (angina, caused by insufficient blood flow to heart) due to pre-existing heart and/or circulation problems (cardiovascular disease)
• If you have a known irregular heart beat (‘long QT syndrome’) or related symptoms, or are taking medicines known to cause the syndrome
• If you are given a rapid intravenous injection (bolus), it may cause decreased blood pressure (hypotension), a sudden brief sensation of heat (flushing), often over the entire body, and an increased heart rate (reflex tachycardia)

When Syntocinon is given to induce and enhance labour:
• It should be given only by intravenous infusion
• The infusion rate should be set to maintain a contraction pattern similar to normal labour and adjusted to individual response. Excessive doses may cause very strong continuous contraction (tetany) and possible bursting (rupture) of the womb with serious complications for your baby (distress or death) and yourself

Take particular care with Syntocinon:
• If you have been warned by a doctor or midwife that normal delivery may be difficult as your baby’s head may be too large to fit through your pelvis (cephalopelvic disproportion)
• If your womb starts to contract less strongly during labour (secondary uterine inertia)
• If you have a mild or moderate pregnancy-induced increase in blood pressure or heart and/or circulation problems (cardiovascular disease)
• If you are over 35 years of age
• If you have had a caesarean section through an incision just above the edge of the bladder (lower segment caesarean section)
• If you have kidney problems (Syntocinon can cause water retention)

If any of these conditions apply to you, tell your doctor as soon as possible.
• Syntocinon may rarely cause abnormal blood clotting, bleeding and anaemia (disseminated intravascular coagulation)
• High doses of Syntocinon may force water from your womb (amniotic fluid) into your blood circulation (amniotic fluid embolism) during labour and/or delivery
• High doses of Syntocinon over a prolonged period while drinking or receiving large volumes of fluid may cause
  - severe abdominal fullness and difficulty in breathing (acute pulmonary oedema)
  - a low level of salt (sodium) in the blood (hyponatraemia)

Taking other medicines
Tell your doctor or health care professional about the other medicines you are taking or have recently taken, including those you may have bought over the counter. It is especially important that your doctor knows if you are receiving any of the following:
• Anaesthetic medicines for local or regional pain relief, in particular epidural anaesthesia (injection of local anaesthetic around the spinal cord) for pain relief during labour: Syntocinon may increase the blood vessel narrowing effect of these medicines (vasoconstriction), and cause an increase in blood pressure
• Medicines called prostaglandins (used to bring on [induce] labour or treat stomach ulcers) and similar drugs: Syntocinon may increase their contractile effect on your womb
• Medicines that can cause an irregular heart beat (prolonged QT interval): Syntocinon may increase this effect
• Gas or vaporous liquid anaesthetics that cause general anaesthesia when inhaled (such as halothane, cyclopropane, sevoflurane or desflurane) may weaken the contractile effects of Syntocinon on your womb

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 (2 years to 17 years)**
There is no information on use in children (2-11 years). Syntocinon is not intended for use in children.

There is no information on use in adolescents (12-17 years). Syntocinon is not intended for use in adolescents

**Pregnancy**
Based on wide experience with the drug, its chemical structure and pharmacological properties, Syntocinon is not expected to present a risk to the baby when used as indicated. It should only be used to initiate labour under medical supervision.

**Breast-feeding**
Syntocinon may be found in small quantities in breast milk but is not expected to have harmful effects because it is rapidly inactivated by your baby’s digestive system. This explains why Syntocinon is safe for your newborn baby.

**Driving and using machines**
Syntocinon may induce contractions. Caution should therefore be exercised when driving or operating machines. Women with contractions should not drive or use machines.

**How to use Syntocinon**
Syntocinon should be administered as an infusion or injection into a vein. It should be administered in a hospital setting where a qualified health care professional can monitor your contractions. See also the section Take special care with Syntocinon.

**How much Syntocinon to use**
Your doctor or health care professional will decide how much Syntocinon to use. For more information please refer to section 7: Information for the health care professional.

**When to use Syntocinon**
Your doctor will decide when to use Syntocinon. You should check with your doctor or health care professional for more information. If you have the impression that the effect of Syntocinon is too strong or too weak, talk to your doctor or health care professional.

**How to use Syntocinon**
Syntocinon is usually diluted before use and given as an intravenous infusion (drip) or injection by a health care professional.

**How long to use Syntocinon**
Your doctor will decide how long you should use Syntocinon. If you are unsure, ask your doctor or health care professional.

**If you have received more Syntocinon than you should**
As this medicine is given to you in hospital, it is very unlikely that you will receive an overdose. Were it to happen, however, it is an emergency that can be handled immediately in the hospital setting.

Anyone accidentally receiving this medicine should visit a hospital accident and emergency department or doctor immediately, if possible with the left-over medicines or empty packet.
Excessive contractions caused by an overdose of Syntocinon may have the consequences mentioned in the sections ‘Take special care with Syntocinon’ and ‘Possible side effects’:

- The placenta may separate too early from the womb (abruption)
- Some of the water around your baby (amniotic fluid) may be forced into your circulation (amniotic fluid embolism)
- Your baby may suffer distress, suffocation or death
- Your womb may tear or burst (rupture)

**If you forget to use Syntocinon**

As you will only be given this medicine by a doctor or health care professional, you are unlikely to miss a dose.

If you have any further questions on the use of this product, ask your doctor or health care professional.

**If you stop using Syntocinon**

Your doctor will decide when you should stop treatment with Syntocinon. If you are unsure, ask your doctor or health care professional.

**Possible side effects**

As with all medicines, side effects may occur with Syntocinon, although not everybody gets them. Your doctor may consider it necessary to treat the side effects of Syntocinon with other medicines.

Some side effects could be serious.

**Some side effects are rare**

The following side effect may affect between 1 and 10 in every 1,000 patients:

- Severe allergic (anaphylactic/anaphylactoid) reaction associated with breathlessness (dyspnoea), low blood pressure (hypotension) or dangerously low blood pressure (shock)

**The proportion of patients who may be affected by the following serious side effects is unknown:**

**Effects in the mother**

- Chest pain due to insufficient blood flow to the heart (angina)
- Irregular heartbeat (long QTc interval)
- Excessive contractions (hypertonicity)
- Continuous contraction (tetany)
- Bursting of the womb (uterine rupture)
- Fluid retention (water intoxication)
- Low sodium (salt) level in the blood (hyponatraemia)
- Acute fluid overload in the lungs (acute pulmonary oedema)
- A sudden brief sensation of heat, often over the entire body (flushing)
- Abnormal clotting, bleeding and anaemia (disseminated intravascular coagulation)
- Swelling of the face, lips, tongue, throat, and/or extremities (possible signs of angioedema)

If you experience any of these, tell your doctor straight away.

**Effects in the baby**

Excessive contractions may cause:

- Low sodium (salt) level in the blood (neonatal hyponatraemia)
- Oxygen starvation (foetal distress)
• Suffocation from too little oxygen and/or too much carbon dioxide (asphyxia)
• Death

If any of these affects are severe, tell your doctor straight away.

**Some side effects are common**
These side effects may affect between 1 and 10 in every 100 patients.
• Headache
• Fast heart beat (tachycardia)
• Slow heart beat (bradycardia)
• Nausea
• Vomiting

If any of these affects you severely, tell your doctor.

**Some side effects are uncommon**
This side effect may affect between 1 and 10 in every 1,000 patients.
• Irregular heartbeat (arrhythmia)

If any of these affects you severely, tell your doctor.

**Some side effects are rare.**
This side effect may affect between 1 and 10 in every 10,000 patients.
• Skin rash

If any of these affects you severely, tell your doctor.

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Storing Syntocinon**
Store in a refrigerator (2-8°C). Keep Syntocinon out of the reach and sight of children.

**Supplier**
SYNTOCINON is supplied in New Zealand by:

Novartis New Zealand Limited

109 Carlton Gore Road
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Auckland 1023

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Telephone 0800 354 335

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