Information for Patients

SYNTOCINON® Ampoules 5 IU/ml concentrate for solution for infusion or solution for intramuscolar injection

SYNTOCINON® Ampoules 10 IU/ml concentrate for solution for infusion or solution for intramuscolar injection

Oxytocin

Read all of this leaflet carefully before you start using 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.
- If you get any side effects, talk to your doctor or nurse. 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 is an injection, which causes contraction of the muscles of the womb. It is identical with oxytocin, a natural hormone released by the pituitary gland.
It may be used:

- To start or help contractions of the womb during labor.
- In patients who are having a miscarriage.
- In the prevention and control of bleeding after delivery.
- During a cesarean section.

2. What you need to know before you use Syntocinon

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

Do not use Syntocinon:

- If you are allergic (hypersensitive) to oxytocin or to any of the other ingredients of this medicine (listed in section 6).

- **If your doctor thinks that inducing or enhancing contractions would be unsuitable for you. For example:**
  - If your contractions of the womb are unusually strong. (hypertonic)
  - If any obstructions may prevent delivery.
  - If your doctor advises against normal labor or vaginal delivery.
  - If your baby is suffering from fetal distress.
- If you have been given medicines called prostaglandins. Syntocinon should not be used for 6 hours after vaginal prostaglandins as the effect of both drugs may be increased (see "Other medicines and Syntocinon").

Warnings and precautions

Talk to your doctor or nurse before using Syntocinon.

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

Syntocinon should not be used for prolonged periods:
- If it fails to increase your contractions
- If you have high blood pressure, protein in the urine, and swelling, a condition known as severe pre–eclamptic toxemia.
- If you have severe problems with heart and/or circulation.

Syntocinon should be used with care:
- If you have a pre-disposition to myocardial ischemia due to pre-existing cardiovascular disease (such as hypertrophic cardiomyopathy, valvular heart disease and/or ischemic heart disease including coronary artery vasospasm), to avoid significant changes in your blood pressure and heart rate.
- If you have known 'long QT syndrome' or related symptoms, or are taking medicines known to prolong the QTc interval.

Take particular care with Syntocinon:
- If you have had a previous caesarean section.
- If you are more than 35 years old.
- If you have been given high doses of Syntocinon over a prolonged period of time.
- If you have mild or moderately raised blood pressure or heart problems.
- If your womb begins to contract less strongly.
- If normal delivery may be difficult due to the small size of your pelvis.
- If your kidneys do not work properly (renal impairment)

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

Other medicines and Syntocinon
Tell your doctor if you are taking, or have recently taken, or might take any other medicines, including any other medicines, medicines obtained without a prescription, medicines obtained abroad, natural products, strong vitamins and minerals as well as dietary supplements.
- When Syntocinon 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 Syntocinon
- The drug should be given with caution in patients taking drugs that are known to interact with the heart muscle activity displayed by ECG.
- Syntocinon should not be given through the same apparatus as blood or plasma, or mixed with any solution containing sodium metabisulphite (a preservative).
- When given during or after epidural anaesthesia, Syntocinon may increase the effects of some drugs given to constrict the blood vessels.

Pregnancy and breast-feeding
Pregnancy
The use of Syntocinon for induction of labor should only be attempted when strictly indicated for medical

reasons, as judged by your physician.

Breast-feeding
Oxytocin (the active ingredient in Syntocinon) may be found in small quantities in mother´s breast milk, but it is not expected to cause harmful effects in the newborn, as oxytocin is deactivated in the gastro intestinal tract of the child.

Fertility
Not applicable for Syntocinon because of the targeted indications.

Driving and using machines
Not relevant.

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.

Syntocinon contains sodium and ethanol
Syntocinon contains less than 1 mmol sodium (23 mg) per ml, i.e. essentially "sodium- free".

This medicine contains 5 mg of alcohol (ethanol) in each dosage unit. The amount in dose of this medicine is equivalent to less than 0.12 ml beer or 0.05 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to use Syntocinon

Syntocinon injection is usually diluted before use and given as an intravenous infusion (drip) into one of your veins. The dose of Syntocinon used varies depending on the reason for its use. When used to start or help contractions during labor the dose is 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 doses are as follows:
To start or help contractions during labor: initially the rate of infusion will be 1-4 milliunits/minute (2 to 8 drops/minute). This may be gradually increased to a maximum rate of 20 milliunits/minute (40 drops/minute). The infusion rate can often be reduced once the contractions reach an adequate level. The contractions and fetal heart rate will be carefully monitored throughout the infusion.

Caesarean Section: 5 IU by intravenous infusion immediately after delivery.
Prevention of bleeding after delivery: 5 IU by intravenous infusion, or to 5 to 10 IU i.m after delivery of the placenta.
Control of bleeding after delivery: 5 IU by intravenous infusion or 5 to 10 IU i.m. In some cases a drip containing 5-20 IU of oxytocin may be used.
Miscarriage: 5 IU by intravenous infusion or 5 to 10 IU i.m. In some cases this may be followed by a drip at 20-40 milliunits/minute.

Renal Impairment
Due to its antidiuretic properties, which may result in water retention with hyponatraemia, the administration of oxytocin is not recommended in patients with severe renal impairment.

Elderly (65 years and over)
There is no information on use in elderly patients.

Children
There is no information on use in children.
If you received more Syntocinon 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. The fatal dose of Syntocinon has not been established.

The symptoms of overdosage are those mentioned under section 4 “Possible side effects”. There have also been reports of separation of the placenta from the uterine wall and/or blocking of maternal circulation by amniotic fluid as a result of overstimulation of the muscles of the womb.

Treatment
When signs or symptoms of overdosage occur during continuous i.v. administration of Syntocinon, the infusion must be discontinued at once and oxygen should be given to the mother.

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

If you stop using Syntocinon
A doctor or a nurse will usually give you this medicine and they will discontinue when appropriate.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some of these side effects may be serious and require medical treatment. You should tell a doctor **immediately** if you experience any of these serious side effects that may affect between 1 and 10 in every 1,000 patients:

- Difficulty breathing (dyspnoea)
- Low blood pressure (hypotension)
- Dangerously low blood pressure (shock)

These may be signs of a serious allergic reaction and shock.

Side effects occurring in the mother include:

Common (occurs in more than 1 in 100 users):
- headache
- abnormally fast heart rate (tachycardia)
- abnormally low heart rate (bradycardia)
- feeling or being sick
- nausea
- vomiting

Uncommon (occurs in fewer than 1 in 100 users):
- irregular heartbeat (arrhythmia)

Rare (occurs in fewer than 1 in 1,000 users):
- skin rash

Not known (frequency cannot be estimated from the available data):
- Chest pain due to insufficient blood flow to the heart (angina)
- Irregular heartbeat (long QTc interval)
- Excessive contractions of the womb (uterine hypertonus)
- Continuous contraction of the womb (tetanic contraction of uterus)
- 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 skin and tissues under the skin or of the mucous membranes (angioedema).

Side effects occurring in the fetus/newborn
- Low sodium (salt) level in the blood (neonatal hyponatraemia)
- Oxygen starvation (fotal distress)
- Suffocation from too little oxygen and/or too much carbon dioxide (asphyxia)
- Death

Some patients may experience spasm of the muscles of the womb at what would normally be considered to be low doses. The use of very high doses may cause very strong contractions of the womb, tearing of the womb, tissue damage and distress to the fotus.

If high doses of Syntocinon 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. Symptoms may include:
headache
anorexia
nausea
vomiting
abdominal pain
sluggishness
drowsiness
unconsciousness
fits
When Syntocinon 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 Syntocinon 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 (see section 2). This may lead to the chest pain or discomfort occuring 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.

The use of medicinal products to induce labor, including Syntocinon might in rare circumstances increase the risk of a severe condition where blood clotting occurs inside the blood vessels after birth.

Tell your doctor or nurse if you suffer from these or any other side effects not mentioned in this leaflet.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

5. How to store Syntocinon

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine 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.
- Store in a refrigerator (2–8°C).
- In-use storage conditions: Do not store above 30°C. Keep ampoules in the outer carton in order to protect from light. The in-use shelf life is 3 months when kept in the outer carton and not stored above 30°C.
- 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. Contents of the pack and other information

What Syntocinon contains:

- The active substance is synthetic oxytocin. Each 1 ml ampoule contains 5IU or 10 IU of oxytocin.
- The other ingredients are sodium acetate trihydrate, glacial acetic acid, chlorobutanol hemihydrate, sodium chloride, ethanol 94% w/w, water for injection.

What Syntocinon looks like and contents of the pack
Solution for infusion or injection.
Clear glass ampoule containing 1ml of a clear colourless, sterile solution.

Syntocinon is available in packs containing 5 ampoules or 10 ampoules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and manufacturer

Manufactured by:
Famar S.A., 63, Ag. Dimitriou Str., 174 56 Alimos, Athens, Greece
or
Alfasigma S.p.A., Via Pontina Km 30.400, 00071 – Pomezia (Rome), Italy

Product authorisation holder:
Alfasigma Spa, Via Ragazzi del ’99, n. 5 - 40133 Bologna (BO) Italy

Local representative:
CD Pharma Srl., Milan (MI), Italy, Tel. +39 02 439 80 539, info@cdpharmagroup.one

This leaflet was last revised