

Syntometrine®

Injection

5 IU synthetic oxytocin / 0.5mg ergometrine maleate

New Zealand Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Syntometrine®.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. Some 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.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you having Syntometrine® against the benefits they expect it will provide.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Syntometrine® is used for

Syntometrine® can be used during and immediately after delivery of a baby to help the birth and to prevent or treat excessive bleeding.

Syntometrine® works by stimulating the muscles of the uterus (womb) to produce rhythmic contractions.

Ask your doctor if you have any questions about why Syntometrine® has been prescribed for you.

Your doctor may have prescribed it for another purpose.

Syntometrine® is only available with a doctor's prescription.

It is not addictive.

Before you are given Syntometrine®

When you must not be given it

You must not be given Syntometrine® if you are allergic to:

- oxytocin
- ergometrine
- any of the other ingredients listed at the end of this leaflet.
- Latex

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

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

You must not have Syntometrine® if you:

- are pregnant or if you are in labour but the baby's shoulder has not yet been delivered
- have severe high blood pressure

- have severe heart, liver or kidney problems
- have eclampsia (a disorder of pregnancy with convulsions, high blood pressure and fluid build-up)
- have a narrowing or blockage of your blood vessels
- have a severe infection

Before you are given it

Tell your doctor if you have any of the following:

- mild or moderate high blood pressure
- an abnormal electrical signal of the heart called "prolongation of the QT interval"
- mild or moderate heart, liver or kidney problems
- any other conditions that affect the heart.
- problems with your lungs
- Raynaud's syndrome (poor circulation which makes the toes and fingers numb and pale)
- you are anaemic (have low iron levels in your blood)
- you have had toxemia during pregnancy

If you are not sure about any of the above, your doctor can advise you.

Tell your doctor if you are allergic to any other medicines, foods, dyes, preservatives or latex.

Your doctor will want to know if you are prone to allergies.

Latex allergy

The active substance oxytocin in Syntometrine might cause a severe allergic reaction (anaphylaxis) in patients with latex allergy.

Taking other medicines

Tell your doctor if you are taking any medicines that may affect your heart, or any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with Syntometrine®. These may include:

- prostaglandins (used to start labour or to treat stomach ulcers)
- vasoconstrictors (used to narrow the blood vessels and decrease the flow of blood) and sympathomimetics (used in the treatment of asthma, nasal congestion and low blood pressure in emergency situations). This includes where these types of medicines are part of a local anaesthetic
- medicines used to treat or prevent angina, e.g. glyceryl trinitrate
- beta-blocker medicines such as propranolol, which are used to prevent migraine, treat high blood pressure, irregular heartbeat, and other heart conditions
- inhalation anaesthetics
- medicines for infections, including ketoconazole, itraconazole, fluconazole, clotrimazole, erythromycin, clarithromycin
- cimetidine (for ulcers and heartburn)
- medicines used to treat HIV/AIDS, including ritonavir, indinavir, nelfinavir
- ergot alkaloids and derivatives, such as methysergide, bromocriptine, and ergometrine
- medicines used to treat migraine such as sumatriptan, and zolmitriptan

Syntometrine with food and drink

Tell your doctor or midwife if you have recently had any grapefruit juice. It is recommended that you do not drink grapefruit juice around the same time as your treatment with Syntometrine® as these may interact.

If you have not told your doctor about any of these things, tell him/her before you are given Syntometrine®.

Tell your doctor if you plan to breast-feed after being given Syntometrine®.

The ergometrine in Syntometrine® may reduce breast milk production, therefore repeated use should be avoided. Your doctor will discuss the potential risks and benefits involved.

How Syntometrine® is given

How much is given

Your doctor will decide the dose of Syntometrine® that you will receive.

How it is given

An injection of Syntometrine® is given intramuscularly (into a muscle) following delivery of the baby's shoulder or immediately after delivery is over.

For prevention or treatment of excessive bleeding, Syntometrine® is given after the placenta has been delivered or when bleeding occurs. If needed, the dose can be repeated after 2 hours.

If you are given too much Syntometrine® (Overdose)

It is unlikely that you will receive an overdose as this medicine is usually administered in a hospital, under the supervision of a doctor.

Some of the symptoms of an overdose include nausea, vomiting, dizziness, light headedness, or shallow breathing.

If you experience severe side effects and think that you or anyone else may have been given too much Syntometrine®, Immediately tell your doctor or telephone the National Poisons Information Centre, Dunedin (telephone number 0800 POISON or 0800 764 766), or go to the Accident and Emergency Department at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep the telephone numbers for these places handy.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are having Syntometrine®.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor or nurse immediately if you notice any of the following symptoms:

- signs of allergy such as rash, itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing or troubled breathing
- nausea (feeling sick) or vomiting
- pain in the abdomen that is different from labour pains
- headache
- dizziness, light headedness or faintness
- slow or irregular heart beat
- chest pain

The above symptoms may be signs of allergy or signs of too much fluid associated with high doses or long infusions.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may happen in some people.

After using Syntometrine®

Storage

Store Syntometrine® in a refrigerator (between 2°C – 8°C).

Do not freeze it.

Protect Syntometrine® from sunlight by keeping the ampoules in the original pack until it is time for it to be given.

Exposure to light may change the solution appearance and product attributes.

Keep the medicine where children cannot reach it.

Once an ampoule is opened, the contents should be used immediately.

Product description

What it looks like

Syntometrine® is available in an uncoloured glass ampoule with blue colour-code rings, containing 1 mL of a clear, colourless solution; 5 ampoules in a cardboard carton.

Ingredients

Each ampoule contains 5 I.U. (International Units) of oxytocin and 0.5 mg of ergometrine maleate. It also contains:

- acetic acid
- chlorobutanol
- maleic acid
- sodium acetate trihydrate
- sodium chloride
- water for injections

Sponsor

Syntometrine® is supplied in New Zealand by:

Max Health Limited
PO Box 44452
Point Chevalier
Auckland
New Zealand 1246
Telephone Ph: (09) 815 2664

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