

Syntometrine®

oxytocin/ergometrine maleate

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.phebra.com.

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.

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 are in labour but the baby's shoulder has not yet been delivered. You must not have Syntometrine if you:

- have severe high blood pressure
- have severe heart, liver or kidney problems
- have high blood pressure, protein in the urine and swelling (pre-eclampsia) with convulsions or coma (eclampsia) during pregnancy or after giving birth
- have a narrowing or blockage of blood vessels
- have a severe infection.

The doctor or nurse will check to ensure the medicine is not past its expiry date and has not been tampered with.

Before you are given it

Tell your doctor if you have any of the following:

- allergy to latex. Syntometrine may cause a severe allergic reaction (anaphylaxis) in patients with latex allergy.
- 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
- poor circulation which makes the toes and fingers numb and pale caused by Raynaud's phenomenon
- 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 or preservatives.

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

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:

- medicines used to start labour or to treat stomach ulcers known as prostaglandins
- medicines used to narrow the blood vessels and decrease the flow of blood such as vasoconstrictors
- sympathomimetic medicines, which are 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
- medicines used for ulcers and heartburn such as cimetidine
- 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.

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 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.

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

Ergometrine derivatives are excreted in breast milk in unknown amounts. Its effects on breast fed newborn are unknown.

The ergometrine in Syntometrine may affect the amount of breast milk produced.

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, tell your doctor or nurse immediately, or telephone the Poisons

Information Centre (telephone number 131 126), or go to Accident and Emergency 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.

While you are being given Syntometrine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you have been given Syntometrine.

Tell any other doctors, dentists, and pharmacists who treat you that you have been given this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you have been given this medicine.

It may affect other medicines used during surgery.

Keep all of your doctor's appointments so that your progress can be checked.

Things to be careful of

Be careful driving or operating machinery until you know how Syntometrine affects you.

This medicine may cause dizziness, light-headedness and blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Taking Syntometrine can start labour. Women having contractions should not drive or use machines.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

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:

- 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 (at 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 IU (International Units) of oxytocin and 0.5 mg of ergometrine maleate. It also contains:

- acetic acid
- chlorobutanol hemihydrate
- maleic acid
- sodium acetate trihydrate
- sodium chloride

- water for injections

Sponsor

Syntometrine is supplied in Australia by:

Phebra Pty Ltd,
19 Orion Road, Lane Cove West,
NSW 2066, Australia
Telephone: 1800 720 020

Australian Registration Number:
Syntometrine AUST R 13396

This leaflet was prepared in 23 May 2019.

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