

Package leaflet: Information for the patient

Syntometrine[®] 500 micrograms/5 IU Solution for Injection ergometrine maleate and 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, nurse or midwife.
- If you get any side effects, talk to your doctor, nurse or midwife. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Syntometrine is and what it is used for
2. What you need to know before you receive Syntometrine
3. How Syntometrine is given to you
4. Possible side effects
5. How to store Syntometrine
6. Contents of the pack and other information

1. What Syntometrine is and what it is used for

The name of your medicine is Syntometrine 500micrograms/5IU Solution for Injection (called Syntometrine in this leaflet). Syntometrine contains two active substances called ergometrine maleate and oxytocin.

Syntometrine is used:

- to help deliver your placenta after giving birth to your baby
- to control bleeding after giving birth.

It works by making the muscles in your womb (uterus) contract.
Syntometrine should be used under medical supervision only.

2. What you need to know before you receive Syntometrine

You must not receive Syntometrine:

- if you are allergic to ergometrine maleate, oxytocin or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant or you are in an early stage of labour and your baby's shoulder has not yet been delivered
- if you have severe high blood pressure
- if you have a problem with your circulation
- if you have a severe heart, liver or kidney problem
- if you have an infection.

Do not have Syntometrine if any of the above apply to you. If you are not sure, talk to your doctor, nurse or midwife before having Syntometrine.

Warnings and precautions

Talk to your doctor, nurse or midwife before you receive Syntometrine if:

- your baby is not in the normal position in your womb
- you have a multiple pregnancy
- you have mild or moderate high blood pressure
- you have a poor diet (malnutrition)

- you have a mild or moderate heart, liver or kidney problem
- you have Raynaud's syndrome (poor circulation which makes the toes and fingers numb and pale). Treatment should be stopped if signs of poor circulation develop
- your bleeding after delivery is not well controlled.

If any of the above apply to you (or you are not sure), talk to your doctor, nurse or midwife before having Syntometrine.

Latex allergy

The active substance oxytocin in Syntometrine 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 Syntometrine

Tell your doctor, nurse or midwife if you are using, have recently used or might use any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because Syntometrine can affect the way some other medicines work. Also some other medicines can affect the way Syntometrine works.

In particular please tell your doctor, nurse or midwife if you have had any of the following:

- anaesthetics which you breathe in to put you to sleep during surgery (e.g. halothane, cyclopropane, sevoflurane, desflurane, isoflurane) as they could decrease the effect of Syntometrine
- prostaglandins (used to start labour or to treat stomach ulcers) and similar drugs as the effects of both drugs may be increased
- 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) as the effect of the drug may be increased. This includes where these types of medicines are part of a local anaesthetic
- medicines that can cause an irregular heartbeat
- antiviral drugs used to treat HIV, AIDS or hepatitis (e.g. ritonavir, indinavir, nelfinavir, delavirdine, nevirapine)
- antifungal drugs (e.g. ketoconazole, itraconazole, voriconazole)
- quinolones (antibacterial drugs, e.g. ciprofloxacin, levofloxacin, ofloxacin)
- certain types of antibiotics (including troleandomycin, erythromycin, clarithromycin, quinupristin, dalfopristin, rifampicin)
- cimetidine (for ulcers and heartburn)
- ergot alkaloids (e.g. methysergide) or ergot derivatives, used to treat headaches and migraines
- triptans (e.g. sumatriptan, zolmitriptan, rizatriptan, almotriptan, eletriptan), used to treat headaches and migraines
- beta-blockers, used to treat certain heart or eye problems, anxiety or prevent migraines
- anti-anginal medicines including glyceryl trinitrate

If any of the above apply to you (or you are not sure), talk to your doctor, nurse or midwife before having Syntometrine.

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.

Pregnancy and breast-feeding

Pregnancy:

You must not receive Syntometrine if you are pregnant or you are in an early stage of labour and your baby's shoulder has not yet been delivered.

If your baby is in a breech position (or any other abnormal position) before birth, Syntometrine will not be given until after your baby has been born.

If you have a multiple pregnancy (e.g. twins, triplets), Syntometrine will not be given until after the last baby has been born.

Breast-feeding:

The ergometrine in Syntometrine may reduce breast milk production, therefore repeated use should be avoided.

Syntometrine contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

3. How Syntometrine is given to you

Syntometrine is usually given by your doctor, nurse or midwife. It is given as an injection into a muscle. The dose may vary but the usual doses are given below.

How much you will have

To help deliver your placenta after giving birth to your baby

The usual dose is 1ml once your baby’s shoulder has been delivered.
If not then, it will be given straight after your baby is completely delivered.

To control bleeding after giving birth

The usual dose is 1ml after you have delivered your placenta, or when bleeding occurs. Syntometrine can be injected into a vein (0.5 to 1 ml) instead of into a muscle in cases of severe bleeding.

If you are given more Syntometrine

If you have too much of this medicine, your doctor, nurse or midwife will treat your symptoms.

If you have any further questions on the use of this medicine, ask your doctor, nurse or midwife.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor, nurse or midwife if you get any of the following, as you may need urgent medical treatment:

- Signs of a severe allergic reaction, such as:
 - swelling of the face, tongue or throat
 - difficulty breathing
 - low blood pressure (which can cause fainting or dizziness and lightheadedness)
 - severe irritation, reddening or blistering of your skin
 - collapse
 - shock
- heart attack (which can cause chest pain or pain down left arm)

Other side effects of Syntometrine include:

- chest pain
- skin rash
- increased blood pressure
- headache
- feeling dizzy
- slow heart beats or your heart beats out of time

- feeling sick (nausea), being sick (vomiting) or tummy pain.

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or midwife. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance,
Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971;
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Syntometrine

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 pack after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 to 8°C). Keep the ampoules in the outer carton in order to protect from light.

Do not use ampoules which have become discoloured.

6. Contents of the pack and other information

What Syntometrine contains

- The active substances are ergometrine maleate and oxytocin.
Each 1ml of the medicine contains 500micrograms of ergometrine maleate and 5 international units (IU) of oxytocin (equivalent to 8.5micrograms oxytocin).
- The other ingredients are sodium chloride, maleic acid, water for injection, chlorobutanol, sodium acetate trihydrate and acetic acid.

What Syntometrine looks like and contents of the pack

Syntometrine is provided as a clear, colourless solution for injection in 1ml ampoules. They come in packs of 5.

Marketing Authorisation Holder

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