ALLIANCE

PATIENT INFORMATION LEAFLET

Syntometrine® 500 micrograms/5IU 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, midwife or pharmacist.
- If you get any side effects, talk to your doctor, midwife or pharmacist. 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

- Syntometrine belongs to a group of medicines called oxytocics. This means it makes the muscles of the uterus (womb) contract.

Syntometrine is used:

- to help the delivery of the placenta
- to prevent or control bleeding after delivery of your baby.

2. What you need to know before you receive Syntometrine

You must not receive Syntometrine:

- if you are allergic to oxytocin, ergometrine or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant or if you are in labour but the baby's shoulder still cannot be seen
- if your womb is not contracting properly
- if you suffer from severe liver, kidney, heart or circulation problems
- if you have very high blood pressure
- if you are suffering from eclampsia or pre-eclampsia (which causes high blood pressure, protein in the urine, swelling)
- if you have a serious infection.

If any of the above applies to you, or if you are not sure, speak to your doctor or midwife before you receive Syntometrine.

Warnings and precautions
Talk to your doctor or midwife before you receive Syntometrine if:
- you have raised blood pressure
- you have liver or kidney problems
- you have any heart problems, including 'long QT syndrome' (irregular heartbeats)
- you have Raynaud's syndrome (poor circulation which makes the toes and fingers numb and pale)

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.

If any of the above applies to you, or you are not sure, speak to your doctor or midwife before you receive 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 or midwife if you are taking or have recently taken any of the following medicines as they may interfere with Syntometrine:
- 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

Please tell your doctor or midwife if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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 if you are in labour but the baby's shoulder still cannot be seen.

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.
Driving and using machines
Taking Syntometrine can start labour. Women with contractions should not drive or use machines.

Syntometrine can cause the side effects of dizziness and low blood pressure (symptoms of which are light-headedness and blurred vision) in some people. If affected you should not drive or use machinery.

Syntometrine contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

3. How Syntometrine is given to you

Your doctor or midwife will decide when and how to treat you with Syntometrine.

The usual dosage is different in the following circumstances:

To help the delivery of the placenta
1ml is injected into a muscle, once your baby's shoulder can be seen or immediately after delivery of your baby. The doctor or midwife will pull gently on the umbilical cord to help deliver the placenta.

To prevent and control bleeding after delivery
1ml is injected into a muscle after the placenta is delivered or when bleeding occurs.

Sometimes Syntometrine is injected into a vein (0.5 to 1 ml) instead of into a muscle but this is not generally recommended.

What to do if you receive more Syntometrine than you should
As this medicine is given to you in hospital, it is very unlikely that you will receive an overdose. If anyone accidentally receives this medicine, tell the hospital accident and emergency department or a doctor immediately. Show any left over medicines or the empty packet to the doctor.

An overdose of Syntometrine could cause:
- feeling or being sick
- a fall or rise in blood pressure (dizziness, light headedness, feeling faint)
- vasospastic reactions (pain or discomfort of your fingers caused by a lack of blood reaching the fingertips)
- difficulty breathing
- fits
- coma.

What to do if you miss a dose
As a doctor or midwife is giving you this medicine, you are unlikely to miss a dose. If you have any worries, tell a doctor or midwife.

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

4. Possible side effects

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

Tell your doctor or contact your nearest hospital straight away if you notice or suspect any of the following symptoms. 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:
- headache
- dizziness
- an irregular or slow heartbeat
- chest pain
- high blood pressure
- feeling or being sick
- stomach pain
- rash

Reporting of side effects
If you get any side effects, talk to your doctor or midwife. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the internet at www.mhra.gov.uk/yellowcard or search for MHRA Yellow card in the Google Play or Apple

App Store. 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.

The hospital pharmacy will store this medicine in a refrigerator between 2° and 8°C and make sure that it is not used after the expiry date on the pack. The expiry date refers to the last day of that month. It will also be kept in the dark. Syntometrine may be stored up to 25°C for 2 months when protected from light, but must then be discarded.

If your doctor decides to stop your treatment, return any unused medicine to the pharmacist. Only keep it if your doctor tells you to.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist on how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Syntometrine contains
The active ingredients in this medicine are oxytocin and ergometrine maleate.
The other ingredients are sodium chloride, maleic acid, water for injections, chlorobutanol, sodium acetate trihydrate and acetic acid.

What Syntometrine looks like and contents of the pack
Syntometrine is a clear, colourless, faintly bluish fluorescent sterile liquid which comes in a 1 ml (millilitre) clear glass ampoule. Syntometrine comes in packs of five ampoules. Each 1ml ampoule contains 500 micrograms of ergometrine maleate and 5 IU (International Units) of oxytocin.

Marketing Authorisation Holder and Manufacturer
The product licence holder is: Alliance Pharmaceuticals Limited, Avonbridge House, Bath Road, Chippenham, Wiltshire, SN15 2BB, UK.

Syntometrine is manufactured by: Panpharma GmbH, Bunsenstraβe 4, 22946 Trittau, Germany.

The information in this leaflet applies only to Syntometrine. If you have any questions or you are not sure about anything, ask your doctor or a pharmacist.

This leaflet was last revised in November 2020

The following information is intended for healthcare professionals only

Syntometrine® 500 micrograms/5IU Solution for Injection ergometrine maleate and oxytocin

Indication	**Active management of 3rd stage of labour**	**Prevention and treatment of postpartum haemorrhage**	
Method of Administration	Intramuscular injection of 1 ml after delivery of the anterior shoulder, or at the latest, immediately after delivery of the child.	Intramuscular injection of 1 ml following expulsion of the placenta, or when bleeding occurs.	
Additional administration notes:	Expulsion of the placenta, which is normally separated by the first strong uterine contraction, should be assisted by controlled cord traction.	In cases of severe haemorrhage due to uterine atony **only**; intravenous administration of Syntometrine is possible (0.5 to 1 ml by slow injection).	

Overdose
In the event of maternal intoxication the most likely symptoms would be those of ergometrine intoxication: nausea, vomiting, hypertension or hypotension, vasospastic reactions, respiratory depression, convulsions, coma. In cases of oral ingestion, although the benefit of gastric decontamination is uncertain, activated charcoal may be given to patients who present within 1 hour of ingesting a toxic dose (more than 125 micrograms/kg in adults) or any amount in a child or in adults with peripheral vascular disease, ischaemic heart disease, severe infection, or hepatic or renal impairment. Alternatively, gastric lavage may be considered in adults within 1 hour of ingesting a potentially life-threatening overdose.

In both acute and chronic poisoning by all routes, attempts must be made to maintain an adequate circulation to the affected parts of the body in order to prevent the onset of gangrene. In severe arterial vasospasm vasodilators such as sodium nitroprusside by intravenous infusion have been given; heparin and dextran 40 have also been advocated to minimise the risk of thrombosis. Analgesics may be required for severe ischaemic pain.

Accidental administration to the newborn infant has been reported and has proved fatal. In these accidental neonatal overdosage cases, symptoms such as respiratory depression, convulsions, cyanosis, oliguria, hypertonia and heart arrhythmia have been reported. Treatment has been symptomatic in most cases; respiratory and cardiovascular support have been required.

Storage
For prolonged periods store between 2° and 8°C. Protect from light. Syntometrine may be stored up to 25°C for 2 months when protected from light, but must then be discarded.