

Ergometrine Injection
ergometrine maleate

Read all of this leaflet carefully before you start receiving 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Ergometrine Injection is and what it is used for

Ergometrine Injection is a medicine that causes contraction of the muscles of the womb and is used:

- in the active management of the third stage of labour
- to control bleeding after the birth.

2. What you need to know before you are given Ergometrine Injection

You must NOT be given Ergometrine Injection:

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

Warnings and precautions:

Talk to your doctor, pharmacist or nurse before being given the injection:

- if you have raised blood pressure
- if you have liver or kidney problems
- if you have an infection
- if you have any heart problems
- if you are going to have an operation under general anaesthetic
- if your baby is in a breech position (or any other abnormal position) before birth, Ergometrine Injection will not be given until after your baby has been born.
- if you have a multiple pregnancy (e.g. twins, triplets), Ergometrine Injection 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 nurse before you receive Ergometrine Injection.

Other medicines and Ergometrine Injection:

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is especially important

with the following medicines as they may interact with your Ergometrine Injection:

- anaesthetics which you breathe in to put you to sleep during surgery as they could decrease the effect of ergometrine (e.g. halothane, cyclopropane, sevoflurane, desflurane, isoflurane)
- 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 or cough or cold remedy
- 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 used to treat ulcers and heartburn
- ergot alkaloids or ergot derivatives, used to treat headaches and migraines (e.g. methysergide)
- triptans used to treat headaches and migraines (e.g. sumatriptan, zolmitriptan, rizatriptan, almotriptan, eletriptan)
- beta-blockers used to treat certain heart or eye problems, anxiety or prevent migraines
- anti-anginal medicines including glyceryl trinitrate
- any medicines that can cause an irregular heartbeat

Ergometrine Injection 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 Ergometrine Injection as these may interact.

Pregnancy and breast feeding:

Pregnancy:

You must not receive Ergometrine Injection 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, Ergometrine Injection will not be given until after your baby has been born.

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

Breast-feeding:

Ergometrine may reduce milk production, therefore repeated use should be avoided.

Driving and using machines:

Ergometrine can start labour. Women with contractions should not drive or use machines.

Ergometrine 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.

3. How Ergometrine Injection is given

Your nurse or doctor will give you the injection.

Your doctor will decide the correct dosage for you and how and when the injection will be given.

If you are given more Ergometrine Injection than you should:

Since the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much.

If you think you have been given too much or if you experience any of the following effects you must tell the person giving you the injection immediately.

- 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 in breathing
- fits
- coma

Ergometrine Injection is not recommended for elderly patients and children.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody 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 possible side effects of Ergometrine Injection include:

- nausea
- vomiting
- abdominal pains
- headache
- dizziness
- ringing in the ears
- skin rashes
- irregular or slowed heart beat
- palpitations (an awareness of your heart beating)
- chest pains
- high blood pressure

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 via the Yellow Card Scheme - Website: 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 Ergometrine Injection

Keep this medicine out of the sight and reach of children.

Your injection will be stored in a refrigerator between 2 °C to 8 °C and protected from light.

Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Ergometrine Injection contains:

The active ingredient is ergometrine maleate 0.05% w.v. Each 1 ml of solution contains 500 micrograms of ergometrine maleate.

The other ingredients are maleic acid and sterile water for injections.

What Ergometrine Injection looks like and contents of the pack:

Ergometrine Injection is supplied in a 1 ml clear glass ampoule, 10 ampoules are supplied in a carton.

The marketing authorisation number of this medicine is: PL 01502/0008R

Marketing Authorisation Holder:

hameln pharmaceuticals ltd
Gloucester
United Kingdom

Manufacturer:

Siegfried Hameln GmbH
Langes Feld 13
31789 Hameln
Germany

hameln rds a.s.
Horná 36
900 01 Modra
Slovak Republic

For any information about this medicine, please contact the Marketing Authorisation Holder

This leaflet was last revised in March 2018.

44173/12/18