

DBL™ Ergometrine Injection

Ergometrine maleate (er-go-MET-reen)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Ergometrine Injection. It does not contain all the available information. It does not take the place of talking to your doctor and pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given ergometrine against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What DBL™ Ergometrine Injection is used for

Ergometrine is given to prevent and/or treat excessive bleeding in the mother after birth or a miscarriage.

This medicine works by contracting the uterus and blood vessels.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

Before you are given DBL™ Ergometrine Injection

When you must not be given it

You must not be given DBL™ Ergometrine Injection if you have an allergy to:

- any medicine containing ergometrine
- any of the ingredients listed at the end of this leaflet
- other medicines belonging to the 'ergot alkaloid' class of medicines (eg ergotamine, dihydroergotamine).

Some of the 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. Other symptoms of an allergic reaction to ergometrine may include sudden and/or severe headache, chest pain, palpitations, slow heart beat, dizziness and/or faintness.

You must not be given this medicine if you:

- are in the first or second stages of labour
- have any retained placenta
- have eclampsia or preeclampsia (very high blood pressure during pregnancy)
- are at risk of miscarriage
- have severe or persistent infection
- have impaired circulation in blood vessels (peripheral vascular disease)
- have heart disease, high blood pressure or a history of high blood pressure
- have impaired liver or kidney function.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have, or have had, any of the following medical conditions:

- disease of the blood vessels of the heart, or other heart problems
- hypertension (or high blood pressure)
- calcium deficiency
- porphyria (a disease of the blood).

Tell your doctor if you plan to breast-feed.

Your doctor will discuss with you the risks and benefits involved.

Tell your doctor if you smoke.

Nicotine may alter the effects of ergometrine.

If you have not told your doctor about any of the above, tell him/her before you are given ergometrine.

Taking other medicines

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

Some medicines and ergometrine may interfere with each other. These include:

- medicines used to treat and/or prevent angina, such as glyceryl trinitrate
- beta-blockers, medicines used to treat or prevent high blood pressure and other heart disorders, eg angina, irregular heartbeats
- bromocriptine, a medicine used to halt lactation, treat hormonal problems or to help manage Parkinson's Disease
- dopamine, a medicine used to treat some heart conditions
- some antibiotics used to treat infection, eg erythromycin, doxycycline or tetracycline
- some general or local anaesthetics
- some medicines used in migraine headaches, eg methysergide and sumatriptan.

These medicines may be affected by ergometrine, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being treated with this medicine.

How DBL™ Ergometrine Injection is given

How much is given

Your doctor will decide what dose you will receive. This depends on your condition. Usually, only a single dose is required for the treatment and prevention of excessive bleeding.

How it is given

Ergometrine is generally given as an injection into a large muscle. In an emergency situation, it may be given as a slow injection into a vein. It must only be given by a doctor or nurse.

If you are given too much (overdose)

As DBL™ Ergometrine Injection is given to you in a hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose.

However, if you experience severe side effects tell your doctor immediately, or call the Poisons Information Centre (in Australia call 13 11 26, in New Zealand call 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are being given DBL™ Ergometrine Injection

Things you must do

If you notice numbness, coldness or tingling in the fingers or toes during treatment with ergometrine, tell your doctor.

Your doctor may decide to discontinue treatment with ergometrine.

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

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given ergometrine.

This medicine helps to stop bleeding in most people, but it may have unwanted side-effects in a few people. 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.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or nurse if you notice any of the following and they worry you:

- mild headache
- nausea
- leg cramps
- nasal congestion
- unusual sweating
- unpleasant taste
- abdominal pain
- mild pain and/or inflammation at the injection site
- ringing in the ears.

The above list includes side effects which are usually mild and short-lived.

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

- signs of an allergic reaction, such as difficulty breathing, sudden and/or severe headache, chest pain, palpitations, slow heart beat, dizziness or faintness
- numbness, coldness or tingling in the fingers or toes
- sudden, severe headache or pressure in the head

- chest pain, angina or palpitations
- decreased, increased or irregular heart rate
- spasm of the oesophagus (food pipe)
- convulsions or seizures
- blood in the urine
- severe pain and/or inflammation at the injection site.
- gangrene
- drowsiness or confusion
- nausea, vomiting, diarrhoea
- decrease or increase in heart rate
- constriction of pupils
- unusual thirst
- difficulty in breathing
- loss of consciousness
- severe cramping of the uterus

The above list includes very serious side effects. You may need urgent medical attention.

Tell your doctor or nurse if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some patients.

After you have been given DBL™ Ergometrine Injection

Storage

DBL™ Ergometrine Injection will be stored in the pharmacy or on the ward. The injection is kept in the refrigerator (between 2 and 8°C) and away from light.

Product description

What it looks like

DBL™ Ergometrine Injection is a colourless or slightly yellowish solution.

Ingredients

DBL™ Ergometrine Injection contains 500 micrograms/mL of ergometrine maleate as the active ingredient. It also contains:

- maleic acid
- water for injections.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Australian Sponsor:

Pfizer Australia Pty Ltd
 Sydney NSW
 Toll Free Number : 1800 675 229
www.pfizer.com.au

DBL™ Ergometrine Injection is available in the following strength:

- 500 mcg/mL ampoule x 5 AUST R 58866

This leaflet was updated in June 2019.