

# DBL™ Ergometrine Injection

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I being given DBL Ergometrine Injection?

DBL Ergometrine Injection contains the active ingredient ergometrine maleate. DBL Ergometrine Injection is used to prevent and/or treat excessive bleeding in the mother after delivery of a baby or a miscarriage. It works by contracting the uterus and blood vessels.

For more information, see Section [1. Why am I being given DBL Ergometrine Injection?](#) in the full CMI.

### 2. What should I know before I am given DBL Ergometrine Injection?

You should not be given DBL Ergometrine Injection if you have ever had an allergic reaction to ergometrine, or other medicines belonging to the ergot alkaloid class of medicines (e.g., ergotamine, dihydroergotamine), or any of the ingredients listed at the end of the CMI.

**Tell your doctor if you have any other medical conditions, take any other medicines, or plan to breastfeed.**

For more information, see Section [2. What should I know before I am given DBL Ergometrine Injection?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with DBL Ergometrine Injection and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How is DBL Ergometrine Injection 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.
- 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.

More instructions can be found in Section [4. How is DBL Ergometrine Injection given?](#) in the full CMI.

## 5. What should I know while being given DBL Ergometrine Injection?

|                                    |  |
|------------------------------------|--|
| <b>Things you should do</b>        | <ul style="list-style-type: none"><li>• Tell your doctor or nurse straight away if you experience numbness, coldness or tingling in the fingers or toes during treatment with ergometrine.</li><li>• Tell any other doctors, dentists and pharmacists who are treating you that you have been given DBL Ergometrine Injection.</li></ul> |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"><li>• DBL Ergometrine Injection will be stored in the hospital pharmacy or in the ward. It is kept in the refrigerator (between 2°C and 8°C) and away from light.</li></ul>  |

For more information, see Section [5. What should I know while being given DBL Ergometrine Injection?](#) in the full CMI.

## 6. Are there any side effects?

- Side effects include mild headache, nausea, leg cramps, nasal congestion, unusual sweating, unpleasant taste, abdominal pain, mild pain and/or inflammation at the injection site and ringing in the ears. These are usually mild and short-lived. Serious side effects include signs of an allergic reaction (such as difficulty breathing, sudden and/or severe headache, chest pain, palpitations, slow heartbeat, 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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# DBL™ Ergometrine Injection

Active ingredient(s): *ergometrine maleate*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Ergometrine Injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being given DBL Ergometrine Injection.**

**Where to find information in this leaflet:**

- [1. Why am I being given DBL Ergometrine Injection?](#)
- [2. What should I know before I am given DBL Ergometrine Injection?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is DBL Ergometrine Injection given?](#)
- [5. What should I know while being given DBL Ergometrine Injection?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I being given DBL Ergometrine Injection?

DBL Ergometrine Injection contains the active ingredient **ergometrine maleate**. Ergometrine is an ergot alkaloid. Ergot alkaloids are usually given to stop

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excessive bleeding that sometimes occurs after delivery of a baby. They work by causing the muscle of the uterus to contract.

**DBL Ergometrine Injection is used to prevent and/or treat excessive bleeding in the mother after delivery of a baby or a miscarriage. It works by contracting the uterus and blood vessels.**

## **2. What should I know before I am given DBL Ergometrine Injection?**

### **Warnings**

**You must not be given DBL Ergometrine Injection if you:**

- are in the first or second stages of labor
- have any retained placenta
- have eclampsia or pre-eclampsia (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
- are allergic to ergometrine, or to other medicines belonging to the ergot alkaloid class of medicines

(e.g., ergotamine, dihydroergotamine), or to any of the ingredients listed at the end of this leaflet.

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 heartbeat, dizziness and/or faintness.

Always check the ingredients to make sure you can use this medicine.

### **Tell your doctor if you:**

- have disease of the blood vessels of the heart, or other heart problems
- have hypertension (high blood pressure)
- have calcium deficiency
- have porphyria (a disease of the blood).
- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes
- smoke (nicotine may alter the effects of ergometrine).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Pregnancy and Breastfeeding

Talk to your doctor if you intend to breastfeed.

### 3. What if I am taking other medicines?

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

**Some medicines may interfere with DBL Ergometrine Injection and affect how it works. 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, e.g., 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, e.g., erythromycin, doxycycline or tetracycline
- some general anaesthetics
- some medicines used in migraine headaches, e.g., 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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Ergometrine Injection.**

## **4. How is DBL Ergometrine Injection 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 DBL Ergometrine Injection**

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.

**If you experience severe side effects and think that you or anyone else may have been given too much DBL Ergometrine Injection you should immediately:**

- tell your doctor or nurse, or
- phone the Poisons Information Centre (**by calling 13 11 26**), or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

## **5. What should I know while being given DBL Ergometrine Injection?**

### **Things you should do**

**Tell your doctor straight away if you:**

- experience numbness, coldness or tingling in the fingers or toes during treatment with ergometrine. Your doctor may decide to stop treatment with ergometrine.

Tell any doctor, dentist or pharmacist that is treating you that you have been given DBL Ergometrine Injection.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how DBL Ergometrine Injection affects you.**

## **Looking after your medicine**

- DBL Ergometrine Injection will be stored in the hospital pharmacy or in the ward. It is kept in the refrigerator (between 2°C and 8°C) and away from light.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### **Side effects**

| <b>Side effects</b>                   | <b>What to do</b>  |
|---------------------------------------|--|
| <b>Administration site disorders:</b> | <b>Speak to your doctor or nurse if you have any of these side effects and they worry you.</b> |

| <b>Side effects</b>   | <b>What to do</b> |
|---|-------------------|
| <ul style="list-style-type: none"> <li>● mild pain and/or inflammation at the injection site</li> </ul> <p><b>Ear disorders:</b></p> <ul style="list-style-type: none"> <li>● ringing in the ears</li> </ul> <p><b>Gastrointestinal disorders:</b></p> <ul style="list-style-type: none"> <li>● nausea</li> <li>● abdominal pain</li> </ul> <p><b>General disorders:</b></p> <ul style="list-style-type: none"> <li>● nasal congestion</li> </ul> <p><b>Musculoskeletal and connective tissue disorders:</b></p> <ul style="list-style-type: none"> <li>● leg cramps</li> </ul> <p><b>Nervous system disorders:</b></p> <ul style="list-style-type: none"> <li>● mild headache</li> <li>● unusual sweating</li> <li>● unpleasant taste</li> </ul> |                   |

## Serious side effects

| Serious side effects  | What to do  |
|---|---|
| <p data-bbox="204 432 596 477"><b>Allergic reaction:</b></p> <ul data-bbox="204 510 772 1301" style="list-style-type: none"><li data-bbox="204 510 772 674">● shortness of breath, wheezing or difficulty breathing</li><li data-bbox="204 696 772 860">● swelling of the face, lips, tongue or other parts of the body</li><li data-bbox="204 882 772 981">● rash, itching or hives on the skin</li><li data-bbox="204 1003 772 1102">● sudden and/or severe headache</li><li data-bbox="204 1124 772 1223">● chest pain, palpitations, slow heartbeat</li><li data-bbox="204 1245 772 1301">● dizziness or faintness</li></ul> <p data-bbox="204 1323 639 1422"><b>Administration site disorders:</b></p> <ul data-bbox="204 1467 655 1630" style="list-style-type: none"><li data-bbox="204 1467 655 1630">● severe pain and/or inflammation at the injection site</li></ul> <p data-bbox="204 1653 612 1697"><b>Cardiac disorders</b></p> <ul data-bbox="204 1731 772 1966" style="list-style-type: none"><li data-bbox="204 1731 772 1843">● chest pain, angina or palpitations</li><li data-bbox="204 1865 772 1966">● decreased, increased or irregular heart rate</li></ul> | <p data-bbox="817 432 1385 645"><b>Tell your doctor or nurse straight away if you notice any of these serious side effects.</b></p> <p data-bbox="817 689 1305 788"><b>You may need urgent medical attention.</b></p> |

| <b>Serious side effects</b>  | <b>What to do</b> |
|--|-------------------|
| <p><b>Gastrointestinal disorders:</b></p> <ul style="list-style-type: none"> <li>● nausea, vomiting, diarrhoea</li> </ul> <p><b>General disorders:</b></p> <ul style="list-style-type: none"> <li>● spasm of the oesophagus (food pipe)</li> <li>● convulsions or seizures</li> <li>● gangrene</li> <li>● drowsiness or confusion</li> <li>● constriction of pupils</li> <li>● unusual thirst</li> <li>● loss of consciousness</li> <li>● severe cramping of the uterus.</li> </ul> <p><b>Nervous system disorders:</b></p> <ul style="list-style-type: none"> <li>● numbness, coldness or tingling in the fingers or toes</li> <li>● sudden, severe headache or pressure in the head</li> </ul> <p><b>Renal and urinary disorders:</b></p> <ul style="list-style-type: none"> <li>● blood in the urine</li> </ul> |                   |

**Tell your doctor or nurse if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects that you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

## **7. Product details**

This medicine is only available with a doctor's prescription.

### **What DBL Ergometrine Injection contains**

|   |                                   |
|---|-----------------------------------|
| <b>Active ingredient<br/>(main ingredient)</b>      | ergometrine maleate               |
| <b>Other ingredients<br/>(inactive ingredients)</b> | maleic acid; water for injections |

**Do not take this medicine if you are allergic to any of these ingredients.**

DBL Ergometrine Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

## **What DBL Ergometrine Injection looks like**

DBL Ergometrine Injection is a colourless or slightly yellowish solution.

DBL Ergometrine Injection: Aust R 58866.

## **Who distributes DBL Ergometrine Injection**

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

[www.pfizermedinfo.com.au](http://www.pfizermedinfo.com.au)

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