

## PRESCRIBING INFORMATION

**Pr Ergonovine Maleate Injection USP**  
0.25 mg/mL  
Sterile Solution

Intramuscular (IM) / Intravenous (IV) Use

Oxytocic Agent

Hikma Canada Limited  
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# Pr ERGONOVINE MALEATE INJECTION USP

## PART I: HEALTH PROFESSIONAL INFORMATION

### SUMMARY PRODUCT INFORMATION

<b>Route of Administration</b>	<b>Dosage Form / Strength</b>	<b>Nonmedicinal Ingredients</b>
Intramuscular / Intravenous (slow)	Solution 0.25 mg/mL	Maleic acid (pH adjustment) Water for Injection

### INDICATIONS AND CLINICAL USE

Ergonovine Maleate Injection USP (ergonovine maleate injection) is indicated for:  
Prevention or treatment of postpartum or post-abortal hemorrhage due to uterine atony.

### CONTRAINDICATIONS

- previous idiosyncrasy or allergic reactions to ergot preparations
- toxemia
- hypertension
- threatened spontaneous abortion
- induction of labor
- Women taking HIV protease inhibitors and non-nucleoside reverse transcriptase inhibitors. (see DRUG INTERACTIONS)

### WARNINGS AND PRECAUTIONS

#### **Serious Warnings and Precautions**

- Because nausea and vomiting may occur, ergonovine should be administered with care to patients under general anesthesia.
- Use with caution in patients with heart disease: coronary vasoconstriction may occur.
- Prolonged therapy may lead to gangrene and other signs of ergotism.

### ***Special Populations***

**Pregnant Women:** The placenta should be delivered, and the possibility of twin pregnancy should be ruled out before ergonovine is administered. Ergonovine should not be administered prior to delivery of the placenta. Administration prior to delivery of the placenta may cause captivation of the placenta or missed diagnosis of a second infant, due to excessive uterine contraction.

**Nursing Women:** Ergometrine enters breast milk in such quantities that may produce ergotism in breast-fed infants. It is therefore contraindicated.

Note: Ergot preparations are frequently given as a single dose postpartum to control hemorrhage. A single dose of ergometrine should not prevent the mother from breastfeeding.

### **ADVERSE REACTIONS**

#### **Adverse Drug Reaction Overview**

Because ergonovine maleate is usually indicated for a short duration, many of the side effects seen with the other ergot alkaloids do not occur.

**CNS:** headache, dizziness, vertigo, hallucinations.

**Cardiovascular:** palpitations, dyspnea, transient chest pain, bradycardia. Hypertension may occur following parenteral administration and is generally due to an undiluted or too rapid I.V. administration or when used in conjunction with regional anesthesia or vasoconstrictors.

**Ear and labyrinth disorders:** tinnitus.

**Gastrointestinal:** nausea and vomiting (usually more common with I.V. administration), diarrhea, abdominal pain, bad taste.

**Respiratory, thoracic and mediastinal disorders:** nasal congestion.

**Others:** diaphoresis, thrombophlebitis, hematuria, water intoxication.

#### **Post-Market Adverse Drug Reactions**

Increased blood creatine, abnormal liver function test, eye movement disorder, muscle spasm.

## DRUG INTERACTIONS

### Serious Drug Interactions

- A significant increase in blood pressure may occur, especially when a regional anesthetic containing a vasopressor drug has been used. Avoid prolonged administration or concomitant use of other vasoconstrictors.

Use of ergonovine maleate in women taking HIV protease inhibitors and non-nucleoside reverse transcriptase inhibitors is contraindicated (see CONTRAINDICATIONS).

## DOSAGE AND ADMINISTRATION

### Dosing Considerations

- In some calcium deficient patients, the uterus may not respond to ergonovine. In such cases, responsiveness can be immediately restored by cautious I.V. injection of calcium salts. (Do not administer I.V. calcium to patients receiving digitalis.)

### Recommended Dose and Dosage Adjustment

- The immediate postpartum dose of ergonovine maleate is 0.2 mg I.M.
- In emergency situations when excessive uterine bleeding has occurred, ergonovine maleate can be administered by slow I.V.
- Dose can be repeated every 2 to 4 hrs, as required, up to a total of 5 doses

### Administration

I.V. doses should be administered over a period of not less than 1 minute. Blood pressure and uterine contractions should be carefully monitored following I.V. administration.

### Dilution

It is recommended that I.V. doses be diluted in 5 mL of the recommended diluent, normal saline solution. The diluted solution can be stored up to 4 hrs, if needed, at room temperature (15°C – 30°C).

As with all parenteral drug products, intravenous admixtures should be usually inspected prior to administration, whenever solution and container permit. Solutions showing haziness or cloudiness, particulate matter, precipitation or discoloration or leakage should not be used.

## OVERDOSAGE

Symptoms and Treatment: Acute overdose may cause chest pain, bradycardia, confusion, drowsiness, miosis, peripheral vasoconstriction, respiratory depression, seizures, tachycardia, nausea and vomiting, loss of consciousness. Other symptoms include numbness and coldness of the extremities, tingling, hypercoagulability, gangrene of the fingers and toes.

Management consists of supportive measures and close supervision including monitoring of vital signs, electrolytes and ECG.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

## **ACTION AND CLINICAL PHARMACOLOGY**

Ergonovine's main action is the production of rhythmic contractions. Parenteral administration causes uterine contractions to begin in 2 to 5 minutes if given I.M. or immediately if given I.V. Uterine contractions persist for 3 hours or longer after I.M. administration and for 45 minutes after I.V. Ergonovine has a more pronounced effect on the uterus than most of the other ergot alkaloids, the difference being more marked on the puerperal uterus than on the normal non-pregnant uterus. The drug has only slight  $\alpha$ -adrenergic blocking activity and its vasoconstrictor effects are less than those of ergotamine.

## **STORAGE AND STABILITY**

Ergonovine Maleate Injection USP must be refrigerated (2 to 8°C). Protect from light. For single use only, discard unused portion.

The diluted solution can be stored up to 4 hrs, at room temperature (15°C – 30°C). Protect from light. (See DOSAGE AND ADMINISTRATION, Dilution).

## **DOSAGE FORMS, COMPOSITION AND PACKAGING**

Each mL of sterile solution contains ergonovine maleate 0.25 mg, maleic acid (pH adjustment), and Water for Injection. Ampoules of 1 mL. Boxes of 5.

**Questions or concerns?**

Contact Hikma Canada Limited at 1-800-656-0793.

This leaflet was prepared by Hikma Canada Limited, Mississauga, ON L5R 3P9

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## REFERENCES

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3. Gizzo S. et al. Which Uterotonic Is Better to Prevent the Postpartum Hemorrhage? Latest News in terms of Clinical Efficacy, Side Effects, and Contraindications: A Systematic Review. *Reproductive Sciences*.2012; 20(9): 1011-1019.
4. Leduc D., Serikas V., Lalonde A.B. Active Management of the Third Stage of Labour: Prevention and Treatment of Postpartum Hemorrhage. *SOGC Clinical Practice Guideline* 2009; 235: 980-993.