



SUMMARY OF PRODUCT CHARACTERISTICS

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1. NAME OF THE MEDICINAL PRODUCT

Ergometrine Injection B.P. 500 micrograms/1ml.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1ml contains 500 micrograms of Ergometrine Maleate B.P.

3. PHARMACEUTICAL FORM

Clear, colourless or faintly yellow solution intended for parenteral administration to human beings.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Ergometrine Injection B.P. 500 micrograms in 1ml is indicated in the active management of the third stage of labour. It is used for the prevention and treatment of postpartum haemorrhage.

4.2. Posology and Method of Administration

Adults: An injection of 500 micrograms is given intramuscularly, usually in combination with oxytocin after delivery of the anterior shoulder. A similar dose with or without oxytocin may be given following delivery of the placenta to prevent or treat postpartum haemorrhage.

In emergencies, Ergometrine Injection may be given intravenously in a dose of 250 to 500 micrograms.

Children: Not recommended. Elderly: Not recommended.

4.3. Contra-Indications

Ergometrine is contra-indicated in patients who are sensitive to ergometrine or any of the ingredients.

First and second stages of labour

Induction of labour

Vascular disease
 Severe cardiac disease
 Severe hypertension
 Eclampsia
 Sepsis
 Impairment of pulmonary function

4.4. Special Warnings and Special Precautions For Use

Ergometrine should be avoided in cases of toxæmia, cardiac disease, hypertension, ~~sepsis~~, hepatic and renal impairment, porphyria, sepsis and multiple pregnancy.

4.5. Interaction with other Medications and other Forms of Interaction

A possible interaction may occur with dopamine.

4.6. Pregnancy and Lactation

The use of ergometrine is entirely restricted to the third stage of labour, otherwise it is not recommended for use during pregnancy or lactation.

4.7. Effects on Ability to Drive and Use Machines

None known.

4.8. Undesirable Effects

Nausea, vomiting, transient hypertension, vasoconstriction, headache, dizziness, tinnitus, abdominal pain, chest pain, palpitation, dyspnoea and bradycardia especially after intravenous administration.

4.9 Overdose

Symptoms of acute poisoning include nausea, vomiting, diarrhoea, extreme thirst, coldness, tingling and itching of the skin, tachycardia, confusion, convulsions and coma. Angina, hypertension or hypotension may also occur.

Treatment consists of supportive and symptomatic measures with intravenous fluids and anticonvulsant therapy as required.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Ergometrine is an ergot alkaloid. It acts directly on uterine muscle to produce sustained contractions and this effect is compatible with the use of ergometrine to control postpartum bleeding.

5.2. Pharmacokinetic Properties

Ergometrine is rapidly absorbed after administration by mouth or by intramuscular injection. Uterine stimulation occurs within about 7 minutes of I.M. injection and within about 1 minute of

I.V. administration. Elimination of ergometrine appears to be principally by metabolism in the liver.

5.3. Pre-clinical Safety Data

No further relevant information other than that which is included in other sections of the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Maleic Acid B.P.
Water for Injections B.P.

6.2. Incompatibilities

None known.

6.3. Shelf-Life

15 months.

6.4. Special Precautions for Storage

Protect from light.
Store at 2 - 8°C.
Do not freeze.
Keep out of reach of children.

6.5. Nature and Content of Container

1ml, clear glass ampoules, glass type 1 Ph. Eur. borosilicate glass packed in cardboard cartons to contain 10 x 1ml ampoules.

6.6. Instructions for Use, Handling and Disposal

For I.M. or I.V. injection.
Use as directed by the physician.
If only part used, discard the remaining solution.
Discard the ampoule if the contents are discoloured.

ADMINISTRATIVE DATA

7. MARKETING AUTHORISATION HOLDER

Antigen International Ltd.,
Roscrea,
Co. Tipperary,
Ireland.

8. MARKETING AUTHORISATION NUMBERS

PL 2848/5915R.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31/1/1990.

10. DATE OF (PARTIAL) REVISION OF TEXT

January 2003.