



## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **PRODUCT SUMMARY**

#### **1. NAME OF THE MEDICINAL PRODUCT**

Ergometrine Injection BP 0.05% w/v.

#### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

500 micrograms of Ergometrine in 1ml.

#### **3. PHARMACEUTICAL FORM**

Sterile Injection.

#### **4. CLINICAL PARTICULARS**

##### **4.1 Therapeutic indications**

Ergometrine Injection is used in the active management of the third stage of labour and in the treatment of post-partum haemorrhage. Ergometrine Injection may be given by intramuscular or intravenous injection.

##### **4.2 Posology and method of administration**

Active Management of the Third Stage of Labour:

Ergometrine Injection is administered (often in combination with synthetic oxytocin 5 units) intramuscularly as a dose of 500 micrograms following the delivery of the anterior shoulder of the infant or immediately after delivery of the baby.

Prevention and Treatment of Postpartum Haemorrhage:

Doses of 200 micrograms to 500 micrograms of Ergometrine are given intramuscularly, following expulsion of the placenta or when bleeding occurs. In emergencies, Ergometrine Injection may be given intravenously at a dose of 250 micrograms to 500 micrograms.

Elderly Patients & Children:

Not recommended.

### **4.3 Contra-indications**

Ergometrine should not be used during the first or second stages of labour, nor should it be administered to patients with hypertension (including that of pre-eclamptic toxemia), occlusive vascular disorders, severe cardiac liver or renal failure or sepsis. The product is also contra-indicated in patients with a known hypersensitivity to ergometrine.

### **4.4 Special warnings and precautions for use**

Ergometrine may give rise to widespread vasoconstriction and rarely acute pulmonary oedema.

Ergometrine should not be given during the first or second stages of labour.

Active management of the third stage of labour requires expert obstetric supervision. Caution is required in patients with mild or moderate hypertension, or with mild or moderate degrees of cardiac, liver or kidney disease (severe forms are contra-indications). Patients with coronary artery disease may be more susceptible to angina or myocardial infarction caused by ergometrine-induced vasospasm.

If in the treatment of postpartum haemorrhage, bleeding is not arrested by the injection, the possibility of a retained placental fragment, or soft tissue injury (cervical or vaginal laceration), or of a clotting defect should be considered and appropriate measures taken before a further injection is given.

Special care should be exercised when ergometrine is given to patients with sepsis or Raynaud's disease.

### **4.5 Interactions with other medicinal products and other forms of interactions**

The vasoconstrictor effects of ergometrine are enhanced by sympathomimetic agents. Halothane anaesthesia may diminish the effects of ergometrine on the parturient uterus.

### **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 and lactation.

### **4.7 Effects on ability to drive and use machines**

Not relevant.

## 4.8 Undesirable effects

*Nervous system disorders:* Headache, dizziness

*Ear & labyrinth disorders:* Tinnitus

*Cardiac disorders:* Cardiac arrhythmias, palpitations, bradycardia, chest pain, coronary arteriospasm with very rare reports of myocardial infarction

*Vascular disorders:* Hypertension, vasoconstriction

*Respiratory disorders:* Dyspnoea, pulmonary oedema

*Gastrointestinal disorders:* Nausea, vomiting, abdominal pain

*Skin & subcutaneous tissue disorders:* Skin rashes

## 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.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Ergometrine is an ergot alkaloid. It is designated as an amine alkaloid because on hydrolysis it yields lysergic acid and an amine.

Ergometrine produces sustained contractions of the uterus. Uterine stimulation occurs within 7 minutes of intramuscular injection and almost immediately following intravenous injection. The sustained uterine contractions produced by ergometrine are effective in controlling uterine haemorrhage.

Ergometrine has weak antagonist actions at dopaminergic receptors in certain blood vessels. It has a partial agonist action in blood vessels (Less than ergotamine) and has little or no antagonist action at  $\alpha$  adrenergic receptors.

### 5.2 Pharmacokinetic properties

Ergometrine is rapidly absorbed after administration by mouth or by intramuscular injection. Uterotonic effect can be observed within 10 minutes following oral administration and within 7 minutes of intramuscular injection. Ergometrine is metabolised in the liver and, judging from the relative duration of action, ergometrine is metabolised and / or eliminated more rapidly than ergotamine.

### **5.3 Preclinical safety data**

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

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Maleic Acid BP QS  
Water for Injections EP to 100%

### **6.2 Incompatibilities**

Ergometrine Injection is incompatible with various drugs according to resulting Ph, temperature and concentration of drugs. Mixing with other drugs in the same syringe should therefore be avoided. Ergometrine may, however, be diluted to a volume of 5mls with 0.9% Sodium Chloride Injection prior to IV administration.

### **6.3 Shelf life**

24 months.

### **6.4 Special precautions for storage**

Ergometrine should be stored below 10°C and protected from light.

### **6.5 Nature and contents of container**

1ml clear type I glass ampoules. Packed in cartons to contain 10 ampoules.

### **6.6 Instructions for use, handling and disposal**

Use as directed by a physician.

## **ADMINISTRATIVE DATA**

## **7. MARKETING AUTHORISATION HOLDER**

Hamel pharmaceuticals ltd  
Gloucester  
UK

## **8. MARKETING AUTHORISATION NUMBER**

1502/0008R

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION**

10th January 1989/ 25th September 2002

**10. DATE OF (PARTIAL) REVISION OF TEXT**

July 2007