1. Name of the Medicinal Product

1.1 (Invented) Name of The Medicinal Product

EMBASSY ERGOMETRINE

1.2 Strength

Each ml contains:

Ergometrine Maleate	BP	0.5 mg
Methyl Hydroxybenzoate (As Preservative)	BP	1.8 mg
Propyl Hydroxybenzoate (As Preservative)	BP	0.2 mg
Water for Injections	BP	q.s.

1.3. Pharmaceutical Dosage Form

Parenteral Preparation (Solution for Injection)

2. Qualitative And Quantitative Composition

Each ml contains:

Ergometrine Maleate	BP	0.5 mg
Methyl Hydroxybenzoate (As Preservative)	BP	1.8 mg
Propyl Hydroxybenzoate (As Preservative)	BP	0.2 mg
Water for Injections	BP	q.s.

3. Pharmaceutical Form

Solution for 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.

4.2 Posology and Method of Administration

Active Management of the Third Stage of Labour:

Ergometrine Injection is administered 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.

Or as directed by the physician.

4.3 Contraindications

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 toxaemia), 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 Warning 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 Interaction with Other Medicinal Products and Other Forms of Interaction

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

None stated

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.

5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Ergot Alkaloid

ATC code: G02AB03

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 α 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

This product has been available for many years and its side effects and clinical profile are well-understood, therefore no further data is provided.

6. Pharmaceutical Particulars

6.1 List of Excipients

Methyl Hydroxybenzoate BP

Propyl Hydroxybenzoate BP

Disodium Edetate BP

Maleic Acid BP

water for Injections BP

6.2 Incompatibilities

NONE

6.3 Shelf Life

<36 Months>

<Use immediately after opening the ampoule>

6.4 Special Precautions for Storage

Store at temperature between 2ºC to 8ºC. Protect from light.

Keep all medicines out of reach of children.

6.5 Nature and Contents of Container

10×1mL ampoules: 1mL amber colour glass ampoule, such 10 ampoules are packed in a plastic tray in carton, along with patient information leaflet.

Primary container : Amber colour glass ampoule

Secondary Container: Plastic Tray, Carton, Pack Insert

6.6 Special Precautions for Disposal and Other Handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Registrant/Sole Agent

EMBASSY PHARMACEUTICALS & CHEMICAL LTD.

41, Ademola Street, South West Ikoyi,

Lagos, Nigeria, Tel.: 01-2900791

8. Manufacturer

LABORATE PHARMACEUTICALS INDIA LIMITED

51, Industrial Area, Gondpur, Paonta Sahib, Himachal Pradesh (INDIA)

HO: E-11, Indl. Área, Panipat – 132103.

laborate@laborate.com

9. Date of Revision of Text

To be given after approval of product

10. Dosimetry (If applicable)

Not applicable

11. Instructions for Preparation of Radiopharmaceuticals (If applicable)

Not applicable