# Summary of Product Characteristics

## 1. Name of the finished pharmaceutical product

Ergometrine Injection Bp 0.5mg/ml

## 2. Qualitative and quantitative composition Composition:

Each ml contains:
Ergometrine Maleate BP.....0.5 mg
Water for Injection BP.....q.s.

For a full list of excipients see section 6.1

## 3. Pharmaceutical form

A clear colorless sterile solution.

## 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

Ergometrine Injection should be used under medical supervision only

***Adults:***

**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 at the latest 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.

**Use in special populations**

***Patients with renal impairment or hepatic impairment***

No studies have been performed in patients with renal or hepatic impairment. However, considering the metabolic pathway of ergometrine, use is contraindicated in severe hepatic and renal impairment and caution is required in mild or moderate hepatic and renal impairment (see sections 4.3 Contraindications, 4.4 Special warnings and precautions for use and 5.2 Pharmacokinetic properties).

***Paediatric population***

No data are available.

***Elderly***

Not applicable.

**Method of administration**

Intramuscular injection is the recommended route.

Intravenous administration of Ergometrine Injection at a dose of 250 micrograms to 500 micrograms (by slow injection) is possible, but should be limited to use only in cases of severe haemorrhage due to uterine atony.

## 4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in this formulation.
- Pregnancy and labour (induction of labour, first stage labour and second stage labour prior to the delivery of the anterior shoulder) due to the risk of uterine hypertonus and associated foetal complications.
- Primary or secondary uterine inertia.
- Severe hypertension, pre-eclampsia, eclampsia.
- Severe cardiac disorders.
- Severe hepatic or renal impairment.
- Occlusive vascular disease e.g. Raynaud's disease / phenomenon
- Sepsis

## 4.4 Special warnings and precautions for use

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

Active management of the third stage of labour requires expert obstetric supervision.

In breech presentations and other abnormal presentations, Ergometrine Injection, should not be given until after delivery of the child, and in multiple births not until the last child has been delivered.

Ergometrine derivatives are excreted in breast milk but in unknown amounts. It can also suppress lactation, so repeated use should be avoided.

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 contraindications.

Patients with coronary artery disease may be more susceptible to angina or myocardial ischaemia and 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.

Ergot alkaloids are substrates of CYP3A4. The concomitant use of Ergometrine Injection with strong CYP3A4 inhibitors such as macrolide antibiotics (e.g. troleandomycin, erythromycin, clarithromycin), HIV protease or reverse transcriptase inhibitors (e.g. ritonavir, indinavir, nelfinavir, delavirdine), or azole antifungals (e.g. ketoconazole, itraconazole, voriconazole) should be avoided, since this can result in an elevated exposure to methylergometrine and ergot toxicity (vasospasm and ischaemia of the extremities and other tissues).Caution should be exercised when Ergometrine Injection is used concurrently with other vasoconstrictors or other ergot alkaloids. Concurrent use of vasoconstrictors and Ergometrine Injection after delivery during anaesthesia may lead to severe postpartum hypertension. Methylergometrine may enhance the vasoconstrictor/vasopressor effects of other drugs such as triptans ($5HT_{1B/1D}$ receptor agonists), sympathomimetics (including those in local anaesthetics), beta-blockers or other ergot alkaloids.

Caution is required when using Ergometrine Injection alone or in combination with prostaglandins and their analogues in the treatment of postpartum atonic uterine haemorrhage.

## 4.5 Interaction with other medicinal products and other forms of interaction

**Concomitant use of Ergometrine Injection with the following medicinal products is not recommended:**

***Vasoconstrictors/Sympathomimetics***

Ergometrine Injection may enhance the vasopressor effects of vasoconstrictors and sympathomimetics, even those contained in local anaesthetics.

***Prostaglandins and their analogues***

Prostaglandins and their analogues facilitate contraction of the myometrium hence Ergometrine Injection can potentiate the uterine action of prostaglandins and analogues and vice versa.

***CYP3A4 inhibitors***

Strong CYP3A4 inhibitors such as protease inhibitors, macrolide antibiotics (e.g. troleandomycin, erythromycin, clarithromycin), HIV protease or reverse transcriptase inhibitors (e.g. ritonavir, indinavir, nelfinavir, delavirdine), azole antifungals (e.g. ketoconazole, itraconazole, voriconazole), quinolones might raise the levels of ergot derivatives, which may lead to ergotism. Combined use with Ergometrine should be avoided. Other weaker CYP3A4 inhibitors (e.g cimetidine, delavirdine, grapefruit juice, quinupristin, dalfopristin) might interact similarly, although possibly to a lesser extent.

***Ergot alkaloids/ergot derivatives***

Concurrent use of other ergot alkaloids (e.g methysergide) and other ergot derivatives can increase the risk of severe and persistent spasm of major arteries in some patients.

***Triptans***

Additive vasoconstriction may occur when ergometrine is concomitantly given with triptans (e.g. sumatriptan, zolmitriptan, rizatriptan, almotriptan, eletriptan).

***Beta-blockers***

Concomitant administration with beta-blockers may enhance the vasoconstrictive action of ergot alkaloids.

***Glyceryl trinitrate and other antianginal drugs***

Ergometrine produces vasoconstriction and can be expected to reduce the effect of glyceryl trinitrate and other antianginal drugs.

**Consideration should be given to the concomitant use of Ergometrine Injection with the following medicinal products:**

***Inhalation anaesthetics***

Inhalation anaesthetics (e.g. halothane, cyclopropane, sevoflurane, desflurane, isoflurane) have a relaxing effect on uterus and produce a notable inhibition of uterine tone and thereby, may diminish the uterotonic effect of ergometrine.

***CYP3A4 inducers***

CYP3A4 inducers (e.g nevirapine, rifampicin) may reduce the clinical effect of ergometrine.

## 4.6 Fertility, pregnancy and lactation

*Pregnancy*

Ergometrine has potent uterotonic activity. Therefore, Ergometrine Injection is contraindicated during pregnancy, during induction of labour, and during first and second stage labour prior to the delivery of the anterior shoulder.

In breech presentation and other abnormal presentations, Ergometrine Injection should not be given before delivery of the child is completed, and in multiple births not before the last child has been delivered.

*Breast-feeding*

Ergometrine derivatives are excreted in breast milk but in unknown amounts. There is no specific data available for elimination of ergometrine partitioned in breast-milk. Ergometrine can inhibit prolactin secretion and in turn can suppress lactation, so its repeated use should be avoided.

## 4.7 Effects on ability to drive and use machines

Receiving Ergometrine Injection can start labour. Women with contractions should not drive or use machines. Patients should be warned of the possibility of dizziness and hypotension.

## 4.8 Undesirable effects

*Immune system disorders*

Anaphylactic/Anaphylactoid reactions with associated symptoms of dyspnoea, hypotension, collapse or shock *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 (see section 4.4 Special warnings and precautions for use)

*Vascular disorders*

Hypertension, vasoconstriction

*Respiratory disorders*

Dyspnoea, pulmonary oedema

*Gastrointestinal disorders*

Nausea, vomiting, abdominal pain

*Skin & subcutaneous tissue disorders*

Skin rashes

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Report any suspected adverse reactions directly via the Blue Form or Med Safety App. Website: fdaghana.gov.gh.

## 4.9 Overdose

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

In cases of oral ingestion, although the benefit of gastric decontamination is uncertain, activated charcoal may be given to patients who present within 1 hour of ingesting a toxic dose (more than 125 micrograms/kg in adults) or any amount in a child or in adults with peripheral vascular disease, ischaemic heart disease, severe infection, or hepatic or renal impairment. Alternatively, gastric lavage may be considered in adults within 1 hour of ingesting a potentially life-threatening overdose.

In both acute and chronic poisoning by all routes, attempts must be made to maintain an adequate circulation to the affected parts of the body in order to prevent the onset

of gangrene. In severe arterial vasospasm, vasodilators such as sodium nitroprusside by intravenous infusion have been given; heparin and dextran 40 have also been advocated to minimise the risk of thrombosis. Analgesics may be required for severe ischaemic pain.

Accidental administration of ergometrine-containing medicinal products to the newborn infant has been reported and has proved fatal. In these accidental neonatal overdosage cases, symptoms such as respiratory depression, convulsions, cyanosis, oliguria, hypertonia and heart arrhythmia have been reported. Treatment has been symptomatic in most cases; respiratory and cardiovascular support have been required.

## 5. Pharmacological properties

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ergot alkaloids

ATC code: G02AB03

Ergometrine produces sustained tonic uterine contraction via agonist or partial agonist effects at myometrial 5-HT2 receptors and alpha-adrenergic receptors. Both upper and lower uterine segments are stimulated to contract in a tetanic manner. Unlike oxytocin ergometrine has an effect on the non-pregnant uterus. Ergometrine inhibits prolactin secretion and in turn can reduce lactation. 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. Compared with other ergot alkaloids, effects of ergometrine on cardiovascular and central nervous system are less pronounced. 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

*Absorption*

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.

*Distribution*

The average steady state volume of distribution of ergometrine in healthy man is reported to be 1.04 L/kg. The plasma protein binding of ergometrine is unknown. Ergometrine is known to cross the placenta and its clearance from the foetus is slow. Concentrations of ergometrine achieved in foetus are not known. Ergometrine is also expected to be excreted in the breast milk and to reduce milk secretion.

*Metabolism/Biotransformation*

Ergometrine is mainly metabolised in the liver by hydroxylation and glucuronic acid conjugation and possibly N-demethylation. Like other ergot alkaloids it is a substrate for CYP3A4 enzymes.

*Elimination*

The plasma half life of ergometrine is reported to be in the range of 30-120 min. When administered orally, the drug is mainly eliminated with the bile into the faeces as 12hydroxyergometrine glucuronide. It is eliminated unchanged in the urine and can be detected up to 8 h after injection.

**5.3 Preclinical safety data**

There are no pre-clinical data of relevance to the prescriber which are additional to those already included in other sections of the Summary of Product Characteristics.

**6. Pharmaceutical particulars**

**6.1 List of excipients**

Maleic acid
Water for injection

**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**

36 months

**6.4 Special precautions for storage**

Ergometrine should be stored between 2° C and 8° C and protected from light.

**Storage out of the refrigerator:**

Ergometrine Injection may also be stored outside of the refrigerator at a temperature of up to 25° C for a maximum 12 weeks, after which it should be discarded. The product should not be placed back into the refrigerator, once it has been kept outside. The storage period must not exceed the shelf-life.

**6.5 Nature and contents of container**

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

### 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. Marketing Authorization Holder

Unicom Chemist Limited

Address: Flour Mill Depot, 214 Winneba Road Next to Takoradi, Chaaba, Ghana

**Manufacturer**

Company name: Centurion Healthcare Pvt. Ltd.
Address: Survey No.494 - 495, Khambhat - Petlad Road, At & Post.- Bamanva - 388 580, Tal.- Khambhat, Dist.- Anand, Gujarat, India

## 8. Marketing Authorization Number

FDA/GD.243-120338

## 9. Date of First Authorization or Renewal

11/03/2025

## 10. Date of Revision of the Text

21/07/2025