

DATA SHEET

SYNTOMETRINE®

**Synthetic oxytocin
Ergometrine maleate**

Composition

Each 1ml ampoule of injectable solution contains 5 I.U. synthetic oxytocin and 0.5mg ergometrine maleate. SYNTOMETRINE injection is a clear, colourless solution, and contains maleic acid as a buffer, pH 3.2. The ampoules have two green identification rings.

Pharmacology

SYNTOMETRINE combines the rapid uterine action of oxytocin, a nonapeptide hormone released by the posterior lobe of the pituitary, with the sustained uterotonic effect of ergometrine.

Following intramuscular administration, the latent period for the occurrence of the uterine response is considerably shorter with SYNTOMETRINE (about 2 ½ minutes) than with ergometrine given alone (about 7 minutes), whereas the uterotonic effect of SYNTOMETRINE lasts for several hours compared with only ½ to 1 hour when oxytocin is given alone.

These properties make SYNTOMETRINE i.m. suitable for the active management of the third stage of labour (see 'Dosage') and for the prevention or treatment of postpartum haemorrhage, particularly in situations where for any reason the intravenous administration of a uterotonic agent is impracticable.

Indications

- Active management of the third stage of labour (as a means to promote separation of the placenta and to reduce blood loss)
- Prevention and treatment of postpartum haemorrhage associated with uterine atony

Contraindications

- Hypersensitivity to any of the components
- Pregnancy, labour (except in second stage of labour following the delivery of the anterior shoulder)
- Severe hypertension, pre-eclampsia, eclampsia.
- Severe disorders of cardiac, hepatic or renal functions; occlusive vascular disease; sepsis.

Precautions

In breech presentation and other abnormal presentations, SYNTOMETRINE should not be given until after delivery of the child is completed. When SYNTOMETRINE is used for the management of the third stage of labour the possibility of multiple pregnancy must be assessed; SYNTOMETRINE should not be given until the last child has been delivered.

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

If in the treatment of postpartum haemorrhage, bleeding is not arrested by the injection of SYNTOMETRINE, 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.

Caution is required in patients with mild or moderate hypertension, or with mild or moderate degrees of cardiac, hepatic or renal disease (severe forms are contraindications). Caution is also required in patients with respiratory disease, chronic anaemia and toxæmia of pregnancy.

Use in Pregnancy: (Category C)

Ergometrine induces uterine contraction and may cause premature or hypertonic labour. Products containing ergometrine must be avoided during pregnancy.

Use in Lactation:

Of the two components, only ergometrine is known to pass into breast milk. The use of SYNTOMETRINE during lactation is not generally recommended.

Interactions

SYNTOMETRINE may enhance the pressor effect of vasoconstrictor drugs (e.g. of sympathomimetic agents contained in local anaesthetics) and potentiate the uterine action of prostaglandins.

Halothane anaesthesia may diminish the uterotonic effect of SYNTOMETRINE.

Adverse effects

SYNTOMETRINE may cause nausea, vomiting, uterine hypertonicity associated with abdominal pain, headache, dizziness and skin rashes. On rare occasions, it may give rise to hypertension, bradycardia, cardiac arrhythmias, chest pain or to anaphylactoid reactions associated with dyspnoea, hypotension, collapse or shock.

Dosage

Active management of third stage of labour:

1 mL intramuscularly following delivery of the anterior shoulder, or immediately after delivery of the child. Expulsion of the placenta, which is normally separated by the first strong uterine contraction following the injection of SYNTOMETRINE should be manually assisted by applying gentle fundal pressure.

Prevention and treatment of postpartum haemorrhage:

1 mL i.m. following expulsion of the placenta, or when bleeding occurs.

If necessary, the injection of 1 mL may be repeated after an interval of not less than 2 hours. The total dose given within 24 hours should not exceed 3 mL.

Intravenous administration of SYNTOMETRINE (0.5 to 1 mL by slow injection) is possible, but not generally recommended. It is advisable to monitor blood pressure during intravenous administration.

Overdosage

No cases of overdosage with SYNTOMETRINE have so far been reported.

The symptoms most likely to occur would be those of acute ergometrine intoxication: nausea, vomiting, hypertension or hypotension, vasospastic reactions, respiratory depression, convulsions, coma. Treatment would have to be symptomatic.

Inadvertent administration to the newborn infant has proved fatal. Other than general resuscitative measures, no treatment is available.

Package quantities

Each pack contains 5 ampoules of 1 mL.

Storage

Store at 2-8°C (Refrigerate, do not freeze). Protect from light

Medicine classification

Prescription Medicine

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