DEMERGIN®

Methylergonovine Maleate

DESCRIPTION: Injection: Clear, colorless to yellowish solution containing 0.2 mg Methylergonovine Maleate and 5 mg Chlorobutanol per ml solution in amber colored ampoule of 1 ml

ACTIONS: DEMERGIN induces a rapid and sustained tetanic uterotonic effect which shortens the third stage of labour and reduces blood loss. The onset of action after IV administration is within 20 – 60 seconds; after IM administration 2 to 6 minutes.

INDICATIONS: Indicated in the prevention or treatment of postpartum or postabortal uterine bleeding due to uterine atony or subinvolution. Its use is not recommended prior to delivery of placenta since placental entrapment may occur.

CONTRAINDICATIONS: Hypertension, pregnancy toxemia, 1 and 2 stage of labour, hypersensitivity, severe cardiac disease, hepatic and renal impairment, induction of labour, cases of threatened spontaneous abortion and in nursing mothers.

ADVERSE REACTIONS: Nausea, vomiting, transient hypertension, dizziness, headache, tinnitus, diaphoresis and palpitation, temporary chest pain, dyspnea and dermatological reactions. Allergic reactions including shock.

WARNING: This drug should not be administered IV routinely because of the possibility of inducing sudden hypertensive and cerebrovascular accidents. If IV administration is considered essential as a life saving measure, DEMERGIN should be given slowly over a period of no less than 60 seconds with careful monitoring of blood pressure.

PARENTERAL USE: Patients have been injured, and some have died because of the injudicious use of oxytoxic agents. Hyperstimulation of the uterus during labor may lead to uterine tetany with marked impairment of the uteroplacental blood flow, uterine rupture, cervical and perineal lacerations, amniotic fluid embolism and trauma to the infant (e.g. hypoxia, intracranial haemorrhage). In same calcium-deficient patients, the uterus may not respond to ergonovine. Responsiveness can be immediately restored by cautious IV injection of calcium salts. Do not give calcium IV to patients receiving digitalis. Oxytoxic agents must be administered under meticulous observation.

PRECAUTIONS: Caution should be exercised in the presence of sepsis, obliterative vascular disease, hepatic or renal impairment. Should be administered with care to patients with anaemia or severe hyperthyroidism. Avoid prolonged use. Discontinue if symptoms of ergotism appear.

DOSAGE AND ADMINISTRATION: Intramuscularly (or intravenously, see WARNING above) exactly after labour: 0.2 mg

DRUG INTERACTION: It enhances the vasoconstrictor / vasopressor effects of other drugs eg sympathomimetics (including sympathomimetics used in local anaesthetics) or ergotamine.

OVERDOSAGE: Symptoms: The main manifestations of serious overdosage are convulsions (acute) and gangrene (chronic). Acute symptoms include nausea, vomiting, diarrhoea, rise or fall in blood pressure, weak pulse, dyspnea, loss of consciousness, numbness and coldness of the extremities, tingling, chest pain, gangrene of the fingers

and toes, hypercoagubility, confusion, excitement, delirium, hallucinations, convulsions and coma.
Treatment: Delayed absorption of ingested drug by giving tap water, milk or activated charcoal, then remove by gastric lavage or emesis followed by catharsis. Treat convulsions symptomatically. Control hypercoagubility by administering heparin and maintain blood-clotting time at approximately three times normal; give vasodilators as antidote. Nitroglycerin (sublingual or IV) is used for coronary vasospasm. Intravenous or intraarterial nitroprusside is the drug of choice for severe vasospasm. Gangrene may require surgical amputation.

STABILITY: Store between (2-8)^{o}C and protected from light.
Shelf-life: 18 months
Solutions for injection should not be used if discolored.

HOW SUPPLIED

Injection in a 1 ml ampoule in a box of 5 ampoules
Injection in a 1 ml ampoule in a box of 6 ampoules
Injection in a 1 ml ampoule in a box of 10 ampoules
Reg. No. : 17160/89 GR

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