Ergonovine Maleate Injection USP
(Ergometrine Maleate)

THERAPEUTIC CATEGORY: OXYTOCIC

PHARMACOLOGY: Ergonovine has a more pronounced effect on the uterus than most of the other ergot alkaloids, the difference being more marked on the puerperal uterus than on the normal non-pregnant uterus. The drug has only slight α-adrenergic blocking activity and its vasoconstrictor effects are less than those of ergotamine. Ergonovine’s main action is the production of rhythmic contractions. Parenteral administration causes uterine contractions to begin in 2 or 3 minutes if given I.M. or 1 minute if given I.V. Uterine contractions persist for 3 hours or longer after oral or I.M. administration and for 45 minutes after I.V.

INDICATIONS: Prevention or treatment of postpartum or post-abortal hemorrhage due to uterine atony.

CONTRAINDICATIONS: Previous idiosyncrasy or allergic reactions to ergot preparations, toxemia, hypertension, threatened spontaneous abortion, induction of labor.

PRECAUTIONS: Because nausea and vomiting may occur, ergonovine should be administered with care to patients under general anesthesia.

Use with caution in patients with heart disease: coronary vasoconstriction may occur.

Prolonged therapy may lead to gangrene and other signs of ergotism.

Drug interactions: A significant increase in blood pressure may occur, especially when a regional anesthetic containing a vasopressor drug has been used. Avoid prolonged administration or concomitant use of other vasoconstrictors.

Pregnancy: The placenta should be delivered, and the possibility of twin pregnancy should be ruled out before ergonovine is administered. Ergonovine should not be administered prior to delivery of the placenta. Administration prior to delivery of the placenta may cause captivation of the placenta or missed diagnosis of a second infant, due to excessive uterine contraction.

Lactation: Ergometrine enters breast milk in such quantities that may produce ergotism in breast-fed infants. It is therefore contraindicated.

Note: Ergot preparations are frequently given as a single dose postpartum to control hemorrhage. A single dose of ergometrine should not prevent the mother from breastfeeding.

ADVERSE EFFECTS: Because ergonovine maleate is usually indicated for a short duration, many of the side effects seen with the other ergot alkaloids do not occur.

CNS: headache, dizziness, vertigo, hallucinations.

Cardiovascular: palpitations, dyspnea, transient chest pain, bradycardia. Hypertension may occur following parenteral administration and is generally due to an undiluted or too rapid I.V. administration or when used in conjunction with regional anesthesia or vasoconstrictors.

Gastrointestinal: nausea and vomiting (usually more common with I.V. administration), diarrhea, abdominal pain.

Others: diaphoresis, thrombophlebitis, hematuria, water intoxication.

OVERDOSE: Symptoms and Treatment: Acute overdose may cause chest pain, bradycardia, confusion, drowsiness, miosis, peripheral vasoconstriction, respiratory depression, seizures, tachycardia, nausea and vomiting, loss of consciousness.

Management consists of supportive measures and close supervision including monitoring of vital signs, electrolytes and ECG.

DOSAGE: The immediate postpartum dose of ergonovine maleate is 200 µg usually administered I.M.

I.V. administration may be used in emergency situations when excessive uterine bleeding has occurred.

I.V. doses should be administered over a period of not less than 1 minute. Blood pressure and uterine contractions should be carefully monitored following I.V. administration. Severe uterine bleeding may require repeated parenteral doses, but injection will rarely be required more often than every 2 to 4 hours (up to a total of 5 doses). To minimize late postpartum bleeding, 200 or 400 µg may be given orally 2 to 4 times daily (every 6 to 12 hours) until the danger of uterine atony has passed – usually 48 hours. In some calcium deficient patients, the uterus may not respond to ergonovine. In such cases, responsiveness can be immediately restored by cautious I.V. injection of calcium salts. (Do not administer I.V. calcium to patients receiving digitalis.)

AVAILABILITY: Each mL of sterile solution contains ergonovine maleate 0.25 mg and maleic acid 5 mg.

Ampoules of 1 mL boxes of 5.

STORAGE: Must be refrigerated (2 to 8°C). Protect from light.

Date of Preparation: March 2009
Alveda Pharmaceuticals Inc.
Toronto, ON, M4S 3C3