Methyldopa Tablets BP 250 mg

Dopamet Comprimidos

Composition: Each film-coated tablet contains:
Methyldopa (as anhydrous) BP 250 mg.
Excipients q.s.
Color: Approved color used.

Therapeutic indications: For the treatment of hypertension.

Dosage and method of administration
Dosage
Use in adults:
Initial dosage: Typically, 250 mg two or three times daily for two days.
Adjustment: Generally adjusted at intervals of not less than two days until an adequate response is obtained.
The maximum recommended daily dose is 3 g. Many patients experience sedation for two or three days when Methyldopa therapy is initiated or when the dose is increased. Therefore, when increasing the dosage, it may be desirable to increase the evening dose first.
Withdrawal of 'Methyldopa' is followed by a return of hypertension, usually within 48 hours. This is generally not complicated by a blood pressure overshoot.
Patients with renal impairment: Methyldopa is largely excreted by the kidney, and patients with renal impairment may respond to lower doses.

Contraindications
'Methyldopa' is contraindicated in patients with:
active liver disease, such as acute hepatitis and active cirrhosis
hypersensitivity to the active substance (including hepatic disorders associated with previous Methyldopa therapy)
depression
concurrent therapy with monoamine oxidase inhibitors (MAOIs)
a catecholamine-secreting tumor, such as pheochromocytoma or paraganglioma
porphyria.

Warnings and special precautions for use
Acquired hemolytic anemia has occurred rarely; if symptoms suggest anemia, hemoglobin and/or hematocrit levels should be determined. If anemia is confirmed, tests for hemolysis should be performed. If hemolytic anemia is present, 'Methyldopa' should be discontinued. Discontinuing therapy—whether or not a corticosteroid is administered—generally resulted in immediate remission. Rarely, however, fatalities have occurred.
Some patients undergoing continued treatment with methyldopa develop a positive Coombs test. Based on reports from various researchers, average incidence rates range between 10% and 20%. A positive Coombs test rarely develops within the first six months of therapy; furthermore, if it has not developed within 12 months, it is unlikely to occur later during continued therapy. Its development is also dose-related, with the lowest incidence occurring in patients receiving 1 g or less of methyldopa per day. The test generally becomes negative within weeks or months after discontinuing methyldopa. It is important to recognize this phenomenon before a patient with a possible pheochromocytoma undergoes surgery. Methyldopa does not interfere with VMA (vanillylmandelic acid) measurements performed using methods that convert VMA into vanillin. Methyldopa is contraindicated for the treatment of patients with a catecholamine-secreting tumor, such as a pheochromocytoma or paraganglioma.

Pregnancy and Lactation
Pregnancy
'Methyldopa' has been used under strict medical supervision for the treatment of hypertension during pregnancy. There has been no clinical evidence that "Methyldopa" causes fetal abnormalities or adversely affects the newborn. Published reports regarding the use of methyldopa throughout all trimesters indicate that, if this drug is used during pregnancy, the possibility of fetal harm appears remote.
Methyldopa crosses the placental barrier and appears in cord blood. Although no obvious teratogenic effects have been reported, the possibility of fetal injury cannot be excluded, and the use of the drug in women who are or may become pregnant requires that the anticipated benefits be weighed against possible risks.
Breastfeeding
Methyldopa appears in breast milk. The use of the medication in nursing mothers requires that the anticipated benefits be weighed against possible risks.

Adverse Effects
Sedation, generally transient, may occur during the initial period of therapy or whenever the dosage is increased. If affected, patients should not attempt to drive or operate machinery. Headache, asthenia, or weakness may be noted as early and transient symptoms.

Overdose
Symptoms
Acute overdose may produce acute hypotension along with other responses attributable to cerebral and gastrointestinal dysfunction (excessive sedation, weakness, bradycardia, dizziness, lightheadedness, constipation, distension, flatulence, diarrhea,
nausea, and vomiting).

Storage: Store below 30ºC in a dry place; protect from light.

Dosage: As directed by a physician.

Keep medicines out of the reach of children.

Presentation: Blister pack of 10 tablets.

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