

Papaverine Hydrochloride

Injection BP

30mg/ml

Para uso SC / IM / IV

Composition:

Each ml contains:

Papaverine Hydrochloride BP 30 mg

Water for Injections BP q.s.

Pharmacotherapeutic category:

IV-4. Cardiovascular system. Vasodilator.

Therapeutic indications:

Papaverine hydrochloride is indicated for:

- Treatment of cerebral, coronary, and peripheral vascular disorders, particularly for the relief of peripheral and cerebral ischemia associated with arterial vasospasm complicated by arrhythmias.
- Antispasmodic for gastrointestinal disorders.
- Diagnosis and treatment of erectile dysfunction.

Contraindications:

Papaverine hydrochloride injection is contraindicated in:

- Cases of known hypersensitivity to papaverine hydrochloride and/or any of the excipients,
- Patients with complete atrioventricular block,
- Patients with conduction depression, as the drug may produce transient ectopic rhythms of ventricular origin.

Undesirable effects:

Autonomic nervous system

Common: headache, dizziness, drowsiness

Uncommon: increased heart rate, dizziness, and syncope (intracavernosal injection)

Other adverse effects were also reported: general malaise, pruritus, hypotension or increased blood pressure, increased depth of breathing, depression, sedation, lassitude, malaise, or lethargy.

Cardiovascular system

Common: cardiac arrhythmias and atrioventricular block

Sistema gastrointestinal

Common: nausea, constipation

Rare: abdominal discomfort, diarrhea, and anorexia.

Hepatic system

Infrequent: hepatitis

Rare: cirrhosis, jaundice

Hepatic reactions due to hypersensitivity may occur (eosinophilia, abnormal liver function tests)

Genitourinary system

Common: ecchymosis, superficial hematoma, and penile erythema

Uncommon: priapism

Skin and appendages

Common: sweating, flushing

Uncommon: skin rash

Local reactions to treatment

Thrombosis, associated with redness, swelling, and pain, was observed at the injection site.

Drug interactions and other interactions:

The effects of papaverine hydrochloride may be slightly potentiated by CNS depressants, and synergism may occur when combined with morphine. Papaverine hydrochloride may interfere with the therapeutic effects of levodopa in patients with Parkinson's disease when the drugs are co-administered. The mechanism of this interaction is unknown, but it has been suggested that papaverine hydrochloride may block dopamine receptors. Papaverine hydrochloride should not be used concomitantly with nicotine, as its vasodilating effect may be diminished or abolished. Calcium channel blockers have a molecular structure similar to that of papaverine; therefore, their effects may be potentiated. As papaverine hydrochloride is a mild antiarrhythmic agent, it may potentiate other similar agents as well as antihypertensive drugs.

Special precautions for use:

Papaverine hydrochloride should be administered with caution to patients with cardiac conduction disorders or cardiovascular disease, and to patients with glaucoma. The injection must be administered by a physician or under immediate medical supervision. Caution should be exercised when administering the drug to patients with reduced gastrointestinal motility and to patients with Parkinson's disease undergoing levodopa therapy. Intravenous administration of the drug must be performed carefully, as arrhythmias and fatal apnea may occur following rapid injection. If signs or

symptoms of hepatic hypersensitivity—such as gastrointestinal symptoms, jaundice, or eosinophilia—occur in patients receiving papaverine hydrochloride, or if liver function test results are abnormal, the drug should be discontinued.

Papaverine hydrochloride should not be added to Lactated Ringer's solution due to the possibility of precipitation.

Pregnancy and breastfeeding

Papaverine hydrochloride should be administered to pregnant women with great caution and only if strictly necessary, as it is unknown whether papaverine hydrochloride can cause harm to the fetus or affect reproductive capacity. It should also be used with caution in breastfeeding women, as it is unknown whether the drug is excreted in breast milk.

Effects on the ability to drive and operate machinery:

No references were found regarding the ability to drive or operate machinery.

Dosage and method of administration:

Papaverine hydrochloride may be administered intramuscularly or via slow intravenous injection.

The intravenous route is recommended when an immediate effect is desired; however, the drug must be injected slowly—over a period of more than 1 or 2 minutes—to avoid serious adverse effects (see precautions and contraindications).

The commonly used adult dose of papaverine hydrochloride is 30 to 120 mg intravenously or intramuscularly, repeated every 3 hours as needed.

For the treatment of cardiac extrasystoles, two doses may be administered at a 10-minute interval. Children may receive 6 mg/kg/day, divided into 4 doses, administered intramuscularly or intravenously. For the treatment and diagnosis of erectile dysfunction, papaverine is administered via intracavernosal injection, starting with a dose of 7.5 mg, which may be increased to 30–60 mg depending on the response. Intracavernosal injection should not be used more than 3 times a week or on two consecutive days.

Overdose:

Symptoms associated with papaverine overdose result from vasomotor instability and include nausea, vomiting, asthenia, central nervous system

depression, nystagmus, diplopia, diaphoresis, flushing, dizziness, and sinus tachycardia. At very high doses, papaverine hydrochloride is a potent inhibitor of cellular respiration and a weak calcium channel antagonist. Following an oral dose of 15 g of papaverine, cases of metabolic acidosis with hyperventilation, hyperglycemia, and hypokalemia have been reported. Following excessive intravenous administration of the drug in animals, cases of ventricular fibrillation, tachyarrhythmias, and convulsions have been reported. A case of coma was also reported in a patient who ingested 200 papaverine tablets (40 mg each = 8 g total).

Treatment

The airway must be protected, and assisted ventilation and perfusion instituted. Meticulously monitor vital signs, as well as blood gases, biochemical parameters, ECG, and other variables. If convulsions occur, they should be treated with diazepam, phenytoin, or phenobarbital. If convulsions are refractory, it may be necessary to induce general anesthesia with thiopental or halothane and paralysis with a neuromuscular blocking agent. For the treatment of hypotension, consider fluid administration, leg elevation, and the use of a vasopressor, such as an inotrope (e.g., dopamine or levodopamine). Calcium gluconate may be useful in treating some of the toxic cardiovascular effects caused by papaverine hydrochloride. Immediately inform your doctor or pharmacist of any undesirable effects not listed in this leaflet.

Storage:

Store in a dry place below 30°C. Protect from light.

Do not use the product after the expiration date printed on the packaging.

Keep out of the reach and sight of children.

Presentation:

10 ampoules of 1 ml packed in a cardboard box with an information leaflet.

Manufactured in India:

