Patient package insert according to Pharmacists' Regulations (Preparations), 1986
This medicine can be sold with a physician's prescription only.

PAPAVERINE HCl STEROP 40mg/2ml

Solution for injection

Active ingredient:
Each 1 ml contains:
Papaverine hydrochloride 20 mg.
For information regarding inactive ingredients and allergens see chapter 2: "Important information about some of the ingredients of the medicine", and chapter 6: "Additional information".

Read all of this leaflet carefully before you start using this medicine.
This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.
This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

1. WHAT IS PAPAVERINE HCl STEROP USED FOR

To relax muscles in the following situations:
- Antispasmodic in visceral spasm, e.g. gastrointestinal colic, biliary and urinary tract spasms.
- Peripheral vascular disease with vasospastic element.
- Vascular spasm associated with acute myocardial infarction, angina pectoris, peripheral and pulmonary embolism.

Therapeutic group:
Antispasmoidic, smooth muscle relaxant.

2. BEFORE USING THE MEDICINE

Do not use this medicine:
- If you are allergic (hypersensitive) to papaverine or any of the other ingredients of this medicine (see section 6).
- Intravenously, if you suffer from complete heart block (complete atrioventricular block).
- In case of serious cardiac insufficiency.
- In case of recent myocardial infarction.
- In case of recent heart attack.
- In case of heart rhythm disorders (abnormally low heart rate).
- In case of increased intracranial pressure.
- In case of liver disease.

Warnings and precautions regarding the use of the medicine:
– Consult your doctor before using Papaverine HCl Sterop 40mg/2ml.
– An intravenous injection administered too quickly may cause heart rhythm disorders (arrhythmias) and fatal apneas.
– Due to the risk of heart rhythm disorders, it should be used with caution in case of heart conduction disorders or unstable cardiovascular conditions.
– Papaverine administration should be discontinued in case of onset of liver toxicity symptoms.
– Patients on chronic Papaverine treatment should undergo regular monitoring of the liver and blood parameters.
– Papaverine should be administered with caution in patients with reduced gastrointestinal motility as they are more easily exposed to digestive disorders.
– In general, there is a risk of irritation or necrosis at the injection site if the administration is too fast or if a significant amount of the substance is injected.
– Intravenous injection is not recommended for children under 15 years of age.

Tests and monitoring
During the treatment period, you may be referred by your doctor to follow-up testing for liver and blood function monitoring.

Interaction with other medicines
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including over the counter medicines and food supplements.
Especially inform your doctor if you are taking:
- Levodopa: The therapeutic effect of levodopa (a Parkinson's disease medicinal product) is decreased in the presence of papaverine.
- Calcium inhibitors: If papaverine is administered with calcium inhibitors (medicinal products for hypertension), these may increase the effect of papaverine.
- Papaverine may increase the effects of similar medicines, such as hypotensive medicines.
- Nicotine may decrease, or even cancel, the vasodilator effect of papaverine.
- Central Nervous System depressants: The effects of papaverine may be slightly increased if combined with central nervous system depressants (tranquilizers), and the combination with morphine may increase these effects.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
There are no adequate human or animal studies addressing the effects of papaverine on fertility or reproductive performance.
There is no data available on the use of papaverine in pregnant women. Papaverine is not recommended for use during pregnancy and in women likely to become pregnant and not using any form of contraception.
It is not known whether papaverine or its derivatives is excreted in breast milk. A risk to the breastfed child cannot be excluded.
The doctor will consider the use of the medicine or the discontinuation of breastfeeding if necessary.

Driving and using machines
Papaverine HCl Sterop 40mg/2ml may cause sleepiness and dizziness. Therefore, patients should take care when driving a vehicle or using machines.

Important information about some of the ingredients of the medicine:
Papaverine HCl Sterop 40mg/2ml contains 44mg/ml glucose monohydrate.

3. HOW TO USE PAPAVERINE HCl STEROP

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
The dosage and form of use will be determined only by your doctor.

Papaverine HCl 40mg/2ml is administrated intravenously or intramuscularly under strict doctor's supervision.

In case of a sign or symptom of hepatic sensitivity in the treated patient, administration of papaverine should be discontinued.
Monitoring by ECG before and during parenteral treatment is recommended.

The usual dose is:
Adults:
30 to 120 mg injected in 1-2 minutes.
Intravenous administration should be used only in cases where immediate effect is needed.
Do not exceed the recommended dose.

If you exceed the recommended dose
If you exceeded the recommended dose or a child accidently swallowed the medicine, contact your doctor or an emergency room immediately, and bring the package of this medicine with you.

Overdose Symptoms
Overdose may cause vasomotor instability (manifesting in hot flashes and massive sweating during the night) accompanied with nausea, vomiting, weakness, central nervous system depression, face flushing, dizziness, apoplexy attacks, heart rhythm disorders and abnormally high heart rate (tachycardia).
Acute overdose results in low blood pressure (hypotension) and cardiorespiratory depression.

Treatment
From the first signs of overdose, treatment should be discontinued and the doctor informed, who will decide on possible hospitalization.

In case of overdose, symptomatic treatment consists in the patient's supported ventilation and blood circulation.
Vital parameters (blood gases and heart conduction) should be monitored.
In case of convulsions, parenteral administration of diazepam, phenytoin or phenobarbital will be started.
In case of refractory convulsions, thiopental and halothane may be used to induce general anesthesia and a neuromuscular blocking agent may be used to produce paralysis.
Hypotension should be treated with administration of intravenous fluids and sympathomimetic agents (noradrenalin) if necessary.
To treat heart disorders, intravenous administration of calcium gluconate with ECG follow-up may be useful.

If you forget to take the medicine
Do not take a double dose to make up for a forgotten dose.
The treatment should be maintained as recommended by the doctor.

If you stop the treatment with injectable Papaverine HCl 40mg/2ml, the targeted symptoms may recur.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.
If you have any further questions regarding the use of this medicine, consult your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Papaverine HCl 40mg/2ml might cause side effects in some patients. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Rare side effects affect 1 to 10 users out of 10,000:
- Increased deep breathing, depression, vertigo, dizziness, headaches, sleepiness, sedated sensation, lassitude, vigilance problems, feeling unwell, weakness and lethargy.
- Increased heart rhythm, arrhythmia (if injected too quickly or with very high doses), atrioventricular block, tachycardia.
- Hypotension or increased blood pressure.
- Constipation, nausea, diarrhea, abdominal pain and anorexia, vomiting.
- Itchiness (pruritis), skin rash.
- General discomfort, redness in face (flushing), sweating, dry mouth and throat.

Very rare side effects, affecting less than 1 in 10,000 users:
- Allergic reactions.

Side effects with unknown frequency:
- Liver toxicity (hepatotoxicity), hepatitis and increased liver enzyme levels (alkaline phosphatases, SGOT).
- Thrombosis at the injection site.

If you experience any side effect, a side effect worsens or you notice side effects not listed in this leaflet, inform your doctor.

Reporting side effects:
You can report side effects to the Ministry of Health by clicking the "report side effects due to medication" in the homepage of the Ministry of Health (www.health.gov.il) referring to an online form for reporting side effects, or by clicking the link:
https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE

* Prevent poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants to prevent poisoning. Do not induce vomiting without explicit instructions from your doctor.
* Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.
* Keep the medicine in the original package in order to protect from light.
* Store below 25°C.
* It is recommended not to refrigerate or freeze this medicine to avoid the risk of precipitation formation.
* This medicine does not contain any preservatives and should be used immediately after opening the ampoule. Do not store the remaining medicine to use at a later time.
* The solution should be inspected visually before administration to detect any possible presence of particulate matter. Do not use the solution if the liquid is not clear.
* Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains:
Glucose monohydrate, disodium edetate, water for injection, nitrogen.

What the medicine looks like and contents of the pack:
A clear or pale yellow solution, with no visible particles.
Papaverine HCl Sterop 40mg/2ml is a solution for injection in 2ml glass ampoules.
Each package contains 10 ampoules or 100 ampoules.

Registration number:
161-86-35093-00

This leaflet was checked and approved by the Ministry of Health in February 2019, and was updated according to MOH instructions in November 2019.

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