PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Papaverine Teva Injection 40 mg / 2 ml

Solution for I.M. or I.V. Injection

Composition
Each 2 ml ampule contains:
Papaverine hydrochloride 40 mg

For information regarding inactive ingredients and allergens, see section 2 - "Important information about some ingredients of the medicine" and section 6 - "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Muscle relaxation in the following situations:
- Visceral spasmotic cramps, e.g. gastrointestinal, biliary and urinary tract spasms.
- Peripheral vascular disease with vasospastic element.
- Vascular spasms associated with acute myocardial infarction, angina pectoris, peripheral and pulmonary embolism.

Therapeutic class: antispasmodics, smooth muscle relaxants.

2. Before using the medicine

Do not use this medicine:
- If you are sensitive (allergic) to papaverine or to any of the other ingredients this medicine contains (see section 6 – "Additional information").
- As an intravenous injection if you have experienced complete heart block (complete atrioventricular block).
- In case of severe heart failure.
- In case of recent myocardial infarction.
- In case of recent heart attack.
- In case of abnormal heart rhythm (abnormally low heart rate).
- In case of increased intracranial pressure.
- In case of liver disease.

Special warnings regarding the use of the medicine
Consult a doctor before using Papaverine Teva Injection.
- A too rapid intravenous injection may lead to heart rhythm disorders (arrhythmias) and fatal apnea.
- Due to the risk of heart rhythm disorders, caution should be exercised in cases of cardiac conduction disorders or unstable cardiovascular diseases.
- Administration of papaverine should be discontinued if symptoms of hepatotoxicity occur.
- Liver and blood tests should be regularly monitored in patients on chronic papaverine treatment.
- Papaverine should be administered with caution to patients with decreased gastrointestinal motility, as they are more easily exposed to digestive disorders.
- Intravenous injection is not recommended for children under 15 years of age.
- In general, there is a risk of irritation or necrosis at the injection site in case of too rapid administration or if too much volume is injected.

Tests and follow-up
- During treatment with the product, you may be referred by the doctor to tests for monitoring blood and liver functions.

Drug interactions
If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, tell the doctor or the pharmacist. Especially inform the doctor or pharmacist if you are taking:
- Levodopa - papaverine reduces the therapeutic effect of levodopa (a drug for treatment of Parkinson's disease).
- Calcium channel blockers - if papaverine is given while being treated with calcium channel blockers (certain antihypertensive agents), it is possible that the effect of papaverine will be increased.
- Papaverine may increase the effects of similar medicinal products such as antihypertensive agents.
- Nicotine - nicotine can reduce or even abolish the vasodilator effects of papaverine.
- Central nervous system modulators - the effects of papaverine may be slightly increased by concomitant use of central nervous system depressants (sedatives), and combination with morphine may increase these effects.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, consult your doctor before taking this medicine.
There are no adequate studies in humans or animals regarding the effects of papaverine on fertility or reproduction.
There are no data on the use of papaverine in pregnant women. Papaverine is not recommended during pregnancy or for women who may become pregnant and do not use contraception.
It is not known whether papaverine or its metabolites pass into breast milk. A risk to the breastfed infant cannot be excluded.
If necessary, the doctor will decide whether it should be used or if breastfeeding should be discontinued.

Driving and operating machinery
Papaverine may cause drowsiness and dizziness. Therefore, caution should be exercised when driving a vehicle or operating machines.

Important information about some ingredients of the medicine
This medicine contains less than 23 mg of sodium in an ampule, and is therefore considered sodium-free.

3. How should you use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.
The dosage and treatment regimen will be determined only by the doctor.
Papaverine Teva Injection should be administered slowly as intravenous or intramuscular injections under the careful supervision of a physician.
Papaverine administration should be discontinued if any sign or symptom of liver tenderness occurs in the treated patient.
It is recommended to perform ECG monitoring before and during parenteral treatment.

The generally accepted dosage is:
Adults:
30-120 mg for injection in 1-2 minutes.
Intravenous injection route should be used only in cases where immediate effect is required.

Do not exceed the recommended dose.

If you accidentally take a higher dosage than needed
If you have taken an overdose or by mistake a child swallowed this medicine, go immediately to the doctor or the emergency room of the hospital and take the package of the medicine with you.

Overdose symptoms
Overdose may cause vasomotor instability (presents as hot flashes and massive sweating during sleep) with nausea, vomiting, weakness, central nervous system depression, redness in the face (flushing), lightheadedness, apoplexy attacks, stroke, heart rhythm disorders and abnormally rapid heart rate (tachycardia).
Acute overdose presents as low blood pressure (hypotension) and cardiorespiratory depression.

Treatment
At the first signs of overdose, treatment with papaverine should be discontinued and the treating physician should be notified; he will decide whether hospitalization is required.
In case of overdose, symptomatic treatment consists of supporting patient ventilation and blood circulation.
Vital signs (blood gas and cardiac conduction) should be monitored.
In case of seizures, parenteral administration of diazepam, phenytoin or phenobarbital should be started.
In case of refractory seizures, thiopental and halothane may be used to induce general anesthesia and neuromuscular blocking agents may be used to cause paralysis.
To treat hypotension, administer intravenous fluids and, if necessary, sympathomimetic agents (noradrenaline).
For treatment of heart disorders, intravenous administration of calcium gluconate and ECG monitoring may be helpful.

If you forget to take Papaverine Teva Injection do not take a double dose to make up for a forgotten dose.
Follow the treatment as recommended by the doctor.

If you stop using Papaverine Teva Injection
The symptoms that you suffered from before starting treatment may recur.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Papaverine Teva Injection may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Rare side effects, affecting 1-10 users out of 10,000:
- Increased depth of breathing, depression, dizziness, vertigo, headache, drowsiness, calming effect (sedation), lassitude, alertness disturbances, malaise, weakness and lethargy.
- Increased heart rate, arrhythmias (too rapid injection or injection of too high doses), atrioventricular block, tachycardia (rapid heartbeat).
- Hypotension or increased blood pressure.
- Constipation, nausea, diarrhea, abdominal pain and anorexia, vomiting.
- Itching (pruritus), rash.
- General discomfort, redness in the face (flushing), sweating, dry mouth and throat.

Very rare side effects, affecting less than 1 out of 10,000 users:
- Hypersensitivity reactions.

Side effects occurring at an unknown frequency:
- Liver toxicity (hepatotoxicity): hepatitis and rise in hepatic enzymes levels (alkaline phosphatase, SGOT).
- Thrombosis at the injection site.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- **Store below 25°C.**
- **Do not freeze.**
- This medicine does not contain any preservatives and should therefore be used one time only, immediately after opening the ampule. Do not store the remaining medicine for later use. The remaining medicine and the rest of the waste should be discarded according to the pharmacist's instructions.
- Do not use this medicine if you notice that there are particles or a precipitate in the ampule. The solution should be examined before use to ensure it contains no visible particles or precipitate. Do not use the solution if it 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:
Sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment), water for injections.

What does the medicine look like and what are the contents of the package:
Each pack contains 10 brown ampules. Each ampule contains 2 ml of light-yellow clear solution.

Name and address of the manufacturer and marketing authorization holder:
Teva Israel Ltd.
124 Dvora HaNevi'a St., Tel Aviv 6944020

The leaflet was revised in January 2022 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 027.68.22028

Preparation and administration of the medicinal product by medical personnel

Before administration, Papaverine Teva Injection should be drawn out according to the rules of good clinical practice, in the most aseptic manner possible, using a sterile syringe, immediately after opening the ampule. The drawn out drug solution should then be administered immediately.
Do not add the papaverine solution to a lactated Ringer's solution as it may form a precipitate.
The solution should be visually inspected prior to administration for any particulate matter.
Do not use the solution if the liquid is not clear. Discard ampules containing visible particles.
This solution does not contain any antimicrobial preservative and is therefore for single use, which is not likely to prevent microorganism growth.
Any unused medicinal product must not be stored for later use.
Any unused product or waste material should be disposed of in accordance with the current regulations.
In general, there is a risk of irritation or necrosis at the injection site in case of too rapid administration or if too much volume is injected.

teva