

## **PACKAGE LEAFLET: Information for the patient**

### **PAPAVERINE**

Solution for injection – 40 mg / 1 ml

(Papaverine hydrochloride)

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Papaverine is and what it is used for
2. Before you take Papaverine
3. How to take Papaverine
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### **1. WHAT PAPAVERINE IS AND WHAT IT IS USED FOR**

Papaverine is an alkaloid present in opium, although it is not related chemically or pharmacologically to the other opium alkaloids.

Papaverine has a direct relaxant effect on smooth muscles, which is attributed partly to its ability to inhibit phosphodiesterase.

It widens the blood vessels including the coronary, cerebral, peripheral and pulmonary arteries; relaxes the smooth musculature of bronchi, digestive system, urethral and biliary system.

Papaverine is indicated in:

- visceral spasms (such as urethral, biliary, or gastrointestinal colics);
- vascular spasms associated with acute myocardial infarction (coronary occlusion);
- angina pectoris;
- peripheral and pulmonary embolism;
- peripheral vascular disease in which there is a vasospastic element;
- certain cerebral angiospastic states.

Your doctor may have given you Papaverine for another reason. Ask your doctor if you want to know why you were given this drug.

## **2. BEFORE YOU TAKE PAPAVERINE**

**Do not take Papaverine if you:**

- are hypersensitive to the drug;
- have complete atrioventricular heart block.

If you think you have any of the above conditions, ask your doctor for advice and follow his instructions.

### **Take special care with Papaverine**

Papaverine should be given with caution to patients with reduced gastrointestinal motility.

Caution is also advised in the presence of cardiac conduction disorders or unstable cardiovascular disease, especially when papaverine is given parenterally.

Papaverine should be used with caution in patients with glaucoma.

Safety and efficacy of papaverine hydrochloride in children have not been established.

If any signs or symptoms of hepatic hypersensitivity occur in patients receiving papaverine, the drug should be discontinued.

### **Taking other medicines**

- When papaverine is used with CNS depressants, additive effects may appear.
- Papaverine may decrease the effect of levodopa.

Ask your doctor or pharmacist for advice if you take concomitantly Papaverine with the above-mentioned drugs.

### **Taking Papaverine with food or drinks**

Not applicable.

### **Pregnancy**

Tell your doctor or pharmacist if you are pregnant or planning to get pregnant and ask him for advice if it can be used during pregnancy.

### **Breastfeeding**

Tell your doctor or pharmacist if you are breastfeeding and ask him for advice if it can be used during this period.

### **Driving and using machines**

The drug may cause dizziness and drowsiness. Therefore, patients should drive or use machines carefully.

## **3. HOW TO TAKE PAPAVERINE**

Always take Papaverine as your doctor has told you. If you are not sure, talk to your doctor or pharmacist. Check with your doctor or pharmacist if you feel that the effects of Papaverine are too strong or too weak

The initial adult dose, by slow intramuscular or intravenous injection, is 30 mg; the following doses: 30 – 120 mg which may be repeated every 3 hours, as necessary.

### **If you take more Papaverine than you should**

If you take more Papaverine than you should, or if the children have been taking this medicine by accident, please contact your doctor, the hospital, or call the emergency to get an opinion of the risk and advice on the actions to be taken.

**If you forget to take Papaverine**

If you forget a dose, take the next dose when it is the normal time to take it.

Do not take a double dose to make up for the forgotten dose.

If you have any further questions on the use of this medicinal product, ask your doctor or pharmacist.

**4. POSSIBLE SIDE EFFECTS**

All medicines may cause side effects. Sometimes they may be serious, sometimes not.

Papaverine may cause:

- in cardiovascular system: increases of the heart rate, a mild increase in blood pressure, orthostatic hypotension;
- in CNS: depression, dizziness, headache, drowsiness, fatigue, lethargy;
- in digestive system: constipation, nausea, diarrhea, dryness of the mouth, anorexia, abdominal disturbances;
- dermatologic effects: flushing of the face, sweating, pruritus;
- haematological effects: eosinophilia.

Jaundice and hepatitis have also been reported.

Inform your doctor if any of the above mentioned side effects bothers you.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**5. HOW TO STORE PAPAVERINE**

Keep out of the reach and sight of children.

Do not use Papaverine after the expiry date which is stated on the package.

Do not store above 25°C.

Store in the original package to protect it from light!

**Attention! The ampoules are for single use only.**

## **6. FURTHER INFORMATION**

### **What Papaverine contains**

**The active substance** is papaverine hydrochloride.

Each ampoule 1 ml contains 40 mg papaverine hydrochloride.

**The other ingredients** are: sodium calcium edetate, hydrochloric acid may be added for pH adjustment, water for injection.

### **Contents of the pack**

Box with 10 ampoules.

### **Marketing Authorisation Holder (MAH) and Manufacturer:**

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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**This leaflet was last revised in January 2024.**