PACKAGE LEAFLET: Information for the patient

DROTAVERINE

Solution for injection – 40 mg / 2 ml

(Drotaverine 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 gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT DROTAVERINE IS AND WHAT IS IT USED FOR

Drotaverine contains the active substance drotaverine hydrochloride.

Drotaverine is a derivative of papaverine that possesses antispasmodic activity due to the phosphodiesterase enzyme inhibition in smooth muscles.

Drotaverine is indicated:

- in spastic conditions of smooth muscles related to biliary tract diseases: cholecystolithiasis, cholecystitis;
- in spastic conditions of smooth muscles of urinary tract: nephrolithiasis, pyeitis (pyelonephritis), cystitis, vesical tenesmus;

- as adjunctive drug: in spastic conditions of smooth muscles of the gastrointestinal tract (gastric and duodenal ulcer disease, spastic conditions of cardia and pylorus of stomach, irritable bowel syndrome, spastic constipation, flatulence) and in spastic conditions of the reproductive tract (dysmenorrhea).

Your doctor may have given Drotaverine for a different purpose. Ask your doctor if you want to know why you were given this medicine.

2. BEFORE YOU TAKE DROTAVERINE

Do not take Drotaverine if:

- you are hypersensitive (allergic) to drotaverine hydrochloride, sodium metabisulphite or to any of the excipients of the solution;
- you have severe renal, hepatic or heart failure.

Drotaverine is contraindicated in children.

Take special care with Drotaverine

Ask your doctor before you take Drotaverine.

Caution is required during administration of Drotaverine to patients with hypotension. Because of the risk of collapse, the drug should be administered intravenously to the lying down patient.

Caution should also be taken for patients with renal or hepatic impairment.

Since drotaverine has been associated with acute attacks of porphyria, it is considered unsafe in porphyric patients.

Drotaverine contains ethanol 96%. It is harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups (such as patients with liver disease, or epilepsy).

Taking other medicines

Inform your doctor or pharmacist if you are taking or have recently taken other medicines, even those without a prescription.

Inhibitors of the enzyme phosphodiesterase, such as papaverine and its derivatives, may reduce

the effect of levodopa.
In case of concomitant taking of Drotaverine and levodopa, patients may experience the intensification of tremors and stiffness.

Taking Drotaverine with food and drinks
Not applicable.

Pregnancy and breastfeeding
Drotaverine hydrochloride crosses the placenta. Given that there is no sufficient evidence, Drotaverine should be used in pregnant women only if the potential benefit to the mother outweighs the risk to which the fetus is exposed.
Because it is not known if drotaverine hydrochloride passes into breast milk, this drug is not recommended during breastfeeding.
Also, because Drotaverine contains ethyl alcohol 96% (ethanol), further care should be taken in pregnant or breastfeeding women.
Seek the advice of a pharmacist or doctor before you take this medicine.

Driving and using machines
Since drotaverine can cause vertigo (dizziness), caution is advised when driving and using machines.

Important information about some of the excipients of Drotaverine
Drotaverine contains sodium metabisulphite and ethyl alcohol (ethanol) 96%.
Sodium metabisulphite may rarely cause severe hypersensitivity reactions and bronchospasm.
Ethyl alcohol, in the amount that is in this drug, is harmful for those suffering from alcoholism.
Also, special care must be taken in pregnant women, those who breastfeed, children and high-risk patients such as those with hepatic insufficiency or epilepsy.

3. HOW TO TAKE DROTAVERINE

Always take Drotaverine as your doctor has advised you.

If you are not sure, talk to your doctor or pharmacist.

The recommended daily dose is 40 - 240 mg and is administered in 1 to 3 divided doses, subcutaneously or intramuscularly.

In cases of acute attacks of gallstones or kidney stones, 40 to 80 mg drotaverine is administered slowly (approximately 30 seconds) intravenously.

In other spastic abdominal pains, 40 to 80 mg drotaverine is administered intramuscularly or subcutaneously. If necessary, the dose can be repeated maximum up to 3 times a day.

Dosage adjustments may be required in patients with renal or hepatic impairment.

If you take more Drotaverine than you should

If you take more Drotaverine than you should, or if the children have wrongly taken this drug, please contact your doctor, hospital, or call the emergency to get an opinion on the risk and advice on the actions to be taken.

There are no known cases of overdose from drotaverine hydrochloride.

If you forget to take Drotaverine

If you forget a dose, take the following dose when it is time to take it usually.

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Drotaverine may cause side effects, although not everyone gets them.

As a result of the use of drotaverine hydrochloride, the following effects have been reported: nausea, headache, vertigo, tachycardia, acute attacks of porphyria and cervical tearing.

If you get any of the side effects, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE DROTAVERINE

Keep out of the reach and sight of children.

Do not use Drotaverine after the expiry date stated on the package.

Do not store above 25ºC.

Keep in the original packaging to protect it from light.

6. FURTHER INFORMATION

What Drotaverine 40 mg / 2 ml solution for injection contains

The active substance is Drotaverine hydrochloride.

Each ampoule 2 ml contains 40 mg of drotaverine hydrochloride.

The excipients are: ethanol 96%, sodium calcium edetate, sodium metabisulphite, sodium citrate, citric acid, hydrochloric acid or sodium hydroxide may be added for pH adjustment, water for injection.

Content of the pack

Box with 10 ampoules of 2 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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