

DRO SPAZ® 40 mg tablets

Drotaverine hydrochloride



Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take DRO SPAZ® carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What DRO SPAZ® is and what it is used for
2. Before you take DRO SPAZ®
3. How to take DRO SPAZ®
4. Possible side effects
5. How to store DRO SPAZ®
6. Further information

1. WHAT DRO SPAZ® IS AND WHAT IT IS USED FOR

DRO SPAZ® tablets is spasmolytic drug product, which relieves or prevents the development of spasms of the various smooth muscle organs regardless on their function and innervation. The spasmolytic action of DRO SPAZ® is many times stronger and much less toxic than that of papaverine and perparin which also act on smooth muscles. This effect furthermore lasts longer.

DRO SPAZ® is used to treat the following conditions:

Spasms, of the smooth muscles, related to the diseases of the biliary system and the gall bladder: gallstone disease, cholecystitis (gall bladder infection).

Spasms of the smooth muscles associated with diseases of urinary tract: nephrolithiasis, ureterolithiasis, pyelitis and cystitis, spasms of the urinary bladder.

DRO SPAZ® can be used as an auxiliary therapy:

Spastic pain conditions of the gastrointestinal tract: gastric and duodenal ulcers, gastritis, enteritis, colitis, irritable bowel syndrome, spastic colitis with constipation.

Tension type headache

Spastic pain conditions in gynaecological diseases: dysmenorrhoea.

2. BEFORE YOU TAKE DRO SPAZ®

Do not take DRO SPAZ®

- **if you are allergic** to the active substance or any of the other ingredients of DRO SPAZ®
- **if you have** severe liver, kidney or heart diseases
- **if you have** cardiac rhythm disorders (AV block II and III degree)
- **children under 1 years** of age should not use this drug

Take special care with DRO SPAZ®:

Before you begin using DRO SPAZ®, inform your doctor if you have any health problems specially, if any of the following apply to you:

The medicinal product should be used with precaution and after careful preliminary assessment of the cardiovascular system in patients with pronounced atherosclerosis of the heart vessels.

The treatment with DRO SPAZ® may lead to symptomatic hypotension (decrease of blood pressure) particularly in patients with low baseline values of the blood pressure. The product should not be used in patients with pronounced hypotension, and particularly in state of shock (systolic blood pressure below 90 mmHg).

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking DRO SPAZ®. DRO SPAZ® contains lactose. In patients hypersensitive to lactose, the medicine may cause gastrointestinal disturbances.

Taking other medicines:

Please inform your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The effect of medicinal products used for treatment of Parkinson's disease (e.g. levodopa) may be reduced in case of combination with DRO SPAZ®.

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine.

Studies conducted in humans and animals have not demonstrated any undesired effects on foetus development. However, this product should be used with precaution during pregnancy, particularly during the first term of the pregnancy.

Breast-feeding:

Due to the lack of sufficient data, the use of this product during breast-feeding is not recommended unless prescribed by your doctor.

Driving and using machines

Due to possible side effects such as dizziness and vertigo resulting from hypotension, you should avoid driving or using machines.

3. How to take DRO SPAZ®

Always follow strictly the instructions provided in this leaflet! The medicine is taken orally with a sufficient amount of liquid.

Recommended dosage:

Adults and children over the age of 12:

The usual dose is 1-2 tablets (40-80 mg) 2-3 times daily.

Children:

From 1 to 6 years of age: ½ tablet (20 mg) 2-3 times daily.

From 6 to 12 years of age: ½ - 1 tablet (20-40 mg) 2-5 times daily

DRO SPAZ® should not be given to children under 1 year.

If you feel that the effect of DRO SPAZ® is too strong or is not strong enough, please discuss it with your doctor or pharmacist.

If you take more DRO SPAZ® than you should:

If you have taken a higher than the necessary dose, immediately contact your nearest hospital casualty department or tell your doctor immediately.

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

If the recommended dosage regimen has been followed, no signs of overdosing will occur. In case of inadvertent intake of large amounts of the product, the following may be observed: decrease of blood pressure, cardiac rhythm disturbances, collapse or respiratory depression.

Treatment in case of overdosing: The treatment should be discontinued immediately. Symptomatic measures may be applied if needed.

If any symptoms of overdosing appear, immediately inform your doctor.

If you forget to take DRO SPAZ®

If you have missed a dose, take the next dose at the right time, do not take a double dose to make up for a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, DroSpaz tablets can cause side effects,

although not everybody gets them. The unwanted side effects are usually very rare and adverse, when the intake of DRO SPAZ® is discontinued.

Rare: headache, dizziness, sleep disorders, nausea, increased heart rate, constipation, hypotension, hot flash, sweateness, skin allergic reactions (rash and itching).

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

5. HOW TO STORE DRO SPAZ® TABLETS

Keep out of the reach and sight of children.

Store the tablets below 30°C, in the original package.

Do not take this medicinal product after the expiry date stated on the carton package.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What DRO SPAZ® tablets contain

- The active substance is drotaverine hydrochloride. Each tablet contains drotaverine hydrochloride 40 mg.
- The other ingredients are: lactose monohydrate, povidone, cellulose microcrystalline, croscarmellose sodium, magnesium stearate.

What DRO SPAZ® tablets look like and contents of the pack

Yellow or bright yellow with a slight green tint tablets, round and flat.

20 tablets in blister of PVC/Al

1 blister with a patient information leaflet, in a carton box.

Marketing Authorization Holder

ADIPHARM EAD

130, Simeonovska shosse Blvd.

Sofia 1700, Bulgaria

Date of the last text revision

May, 2011