

DRO SPAZ 40 mg/ 2 ml, solution for injection

Drotaverine hydrochloride



adipharma

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor pharmacist or nurse.
- 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.
- If any adverse drug reaction gets serious or you notice other, unlisted in this leaflet adverse reactions, please inform your doctor, pharmacist or nurse. Please see point 4.

What is in this leaflet:

1. What DRO SPAZ is and what it is used for
2. What you need to know before you take DRO SPAZ
3. How to take DRO SPAZ
4. Possible side effects
5. How to store DRO SPAZ
6. Contents of the pack and other information

1. What DRO SPAZ is and what it is used for

DRO SPAZ solution for injection lowers the smooth muscle tone of the viscera and the blood vessels by inhibiting (suppressing) the so-called enzyme phosphodiesterase. Upon intravenous administration, the onset of the spasmolytic effect is rapid.

DRO SPAZ is used for

- In spasms of the smooth muscles associated with disorders of the gall bladder and the biliary ways: stones in the gall bladder or the biliary ways, inflammation of the gall bladder or the biliary ways.
- In spasms of the smooth muscles in renal disorders and disorders of the bladder and the urinary tract: stones in the kidneys and the urinary tract, inflammation of the kidneys and the urinary tract, spasm of the bladder.
- In uncomplicated labour in the phase of cervical dilation for decrease of the dilation duration and the whole labour duration.

When oral (through the mouth) intake is not possible, DRO SPAZ solution for injection may be also used in the following cases:

- Spasm of the smooth muscles of the gastrointestinal tract: gastric and duodenal ulcer, gastritis (inflammation of the stomach), spasm of the upper and the lower stomach muscles, bowel inflammation.
- In gynecological disorders: dysmenorrhea (painful periods) and relief of severe spastic pain during labour.

2. What you need to know before you take DRO SPAZ

DRO SPAZ should not be used in:

- allergy (hypersensitivity) to the active substance (drotaverine hydrochloride) or to any of the excipients (especially to sodium metabisulfite).
- severe liver, renal and heart failure, conductivity disorders of the heart (atrio-ventricular block).
- Children.

Take special care with Dro Spaz

You must talk to a doctor pharmacist or nurse before you take Dro Spaz.

In case of low blood pressure this product should be administered with caution.

DRO SPAZ contains sodium metabisulfite which may cause allergic reactions, including anaphylactic symptoms and bronchospasm in predisposed patients, especially those with history of asthma or allergy. In case of hypersensitivity to sodium metabisulfite, the administration of the medicinal product is contraindicated (see the text above). Drotaverine hydrochloride should be injected to pregnant women with caution.

Children and adolescents

This medicinal product should not be administered to children.

Other medicines and Dro Spaz

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Drotaverine hydrochloride reduces the anti-Parkinson effect of levodopa, which results in enhancement of tremor (shaking) and rigidity (constant resistance to passive movement of extremities).

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.

Pregnancy: The studies in humans and animals did not show adverse effects on fetal development. Nevertheless, as a precaution, the product should be administered during pregnancy only after careful assessment of the benefit/risk ratio by your doctor.

Breast-feeding: Due to lack of adequate data, the use of the product during breast-feeding is not recommended.

Driving and using machines

You should avoid performing potentially hazardous activities such as driving and using machines.

Important information about some of the ingredients of DRO SPAZ

DRO SPAZ contains sodium metabisulfite which may cause allergic reactions, including anaphylactic symptoms and bronchospasm in predisposed patients, especially those with history of asthma or allergy (see the text above). If you are aware that you suffer from any listed side effects, please inform your doctor about this before using this medicine.

3. How to use dro spaz

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

DRO SPAZ solution for injection is administered intramuscularly (in the muscles) or intravenously (in the veins).

This medicinal product will be given to you by a health professional who will determine the dosage, route of administration and treatment duration.

The usual daily dose in adults is 40 - 240 mg, divided in 1-3 intramuscular applications.

In case of biliary or renal colics, the dose is 40-80 mg administered intravenously, alone or in combination with analgesics (painkillers).

In case of uncomplicated labour in the phase of cervical dilation for decrease of the dilation duration and of the whole labour duration the dose is 40 mg intramuscularly. If necessary, this dose may be repeated every 2 hours (the maximum daily dose is 240 mg)

If you are given more DRO SPAZ than you should

This medicinal product will be given to you by a doctor and that minimizes the risk of overdose.

If in spite of this, you would inadvertently be given a higher than the required dose you would be subjected to continuous medical surveillance and, if necessary, adequate treatment would be initiated.

Check with your doctor if you are not sure or have any further questions regarding your treatment with this medicinal product.

If you forget to use DRO SPAZ

Do not take a double dose to make up for a forgotten dose, use a medicine in next intake.

4. Possible side effects

Like all medicines, DRO SPAZ solution for injection can cause side effects, although not everybody gets them.

The adverse drug reactions are classified by frequency:

Very common: may affect more than 1 in 10 patients;

Common: may affect up to 1 in 10 patients;

Uncommon: may affect up to 1 in 100 patients;

Rare: may affect up to 1 in 1,000 patients;

Very Rare: may affect up to 1 in 10,000 patients;

Unknown (frequency cannot be estimated from the available data).

The following undesirable effects have been observed:

Rare: cases of nausea, constipation, headache, dizziness, insomnia, palpitation, low blood pressure, allergic reactions, especially in patients with increased susceptibility (hypersensitivity) to bisulfites, reddening, pain and edema around the site of injection are reported.

Unknown (frequency cannot be estimated from the available data): Reported cases with non-fatal and fatal anaphylactic shock in patients used this medicine.

Reporting of suspected side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system.

Be reporting side effects you can help provide more information on the safety of this medicine.

5. How to store DRO SPAZ

Keep this medicine out of the sight and reach of children!

Store at temperature below 30°C in a place protected from light.

The medicinal product should not be used after the expiry date which is stated on the package. The expiry date refers to the last day of that month.

Do not use DRO SPAZ if you notice that the solution is turbid, contains visible particles or is discoloured.

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. Contents of the pack and other information

What DRO SPAZ contains

- The active ingredient is drotaverine hydrochloride. 1 ml of the solution contains 20 mg drotaverine hydrochloride.
- The other ingredients are sodium metabisulfite, ethanol (96%) and water for injections.

What DRO SPAZ looks like and contents of the pack

DRO SPAZ solution for injection is clear yellow liquid in amber glass ampoules.

Each ampoule contains 2 ml of the solution. Each pack (carton box) contains 10 ampoules.

Marketing authorisation holder and manufacturer

ADIPHARM LTD.

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