

Package leaflet: Information for the user
(OTC medicine*)

No-Spa, 40 mg tablets
Drotaverine hydrochloride

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

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if symptoms worsen or do not improve or if you do not feel better or if you feel worse.

What is in this leaflet

1. What No-Spa is and what it is used for
2. What you need to know before you take No-Spa
3. How to take No-Spa
4. Possible side effects
5. How to store No-Spa
6. Contents of the pack and other information

1. What No-Spa is and what it is used for

This medicine is indicated for the treatment of smooth muscle contractions (felt as recurrent stomach pain) in the gastrointestinal tract, gall bladder and urinary tract.

2. What you need to know before you take No-Spa

Do not take No-Spa

- if you are allergic to drotaverine or any of the other ingredients of this medicine (listed in section 6.1);
- if you have severe kidney, liver or heart failure;
- if you are breast-feeding.

No-Spa is contraindicated for children under the age of 1.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using No-Spa.

As blood pressure may drop as a side effect, the medicine must be taken with caution in the case of low blood pressure.

Other medicines and No-Spa

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

In the case of concomitant use with other medicines administered for a long time, talk to your doctor for advice before taking No-Spa.

Caution is advised with the concomitant use of levodopa, as the antiparkinsonian effect of levodopa may be reduced and muscle rigidity and tremors may worsen.

Pregnancy and breast-feeding

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

* Clarification – 20 tbl and 24 tbl per pack – OTC medicine
100 tbl per pack – prescription medicine

Pregnancy

Talk to your doctor or pharmacist before using this medicine.
Caution is advised when taking this medicine during pregnancy.

Breast-feeding

The use of this medicine while breast-feeding is not recommended.

Driving and using machines

In general, recommended doses of No-Spa have no influence on the ability to drive and use machines. If side effects occur, ability to drive should be assessed individually. In the case of dizziness, avoid driving or operating moving machinery.

No-Spa contains lactose

No-Spa contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

3. How to take No-Spa

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

Usual dose

Adults: orally 3...6 tablets in a day, divided between 2...3 doses.

Do not exceed the recommended dose. If symptoms do not improve, talk to your doctor.

Check with your doctor or pharmacist if you are not sure.

If you take more No-Spa than you should

Based on the data available in published literature and based on reports of side effects, an overdose of drotaverine may cause weakness, malaise, dizziness, vomiting, headache, a drop in blood pressure and sleepiness. Heart rhythm and conduction disorders, incl. potentially fatal complete bundle block and cardiac arrest have also been reported.

In the case of accidental or intentional overdose, contact your doctor immediately.

If you forget to take No-Spa

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

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following breakdown by frequency is used to assess adverse reactions:

Very common:	more than 10% (> 1/10)
Common:	1...10% (> 1/100, <1/10)
Uncommon:	0.1...1% (> 1/1000, <1/100)
Rare:	0.01...0.1% (> 1 / 10,000, <1 / 1,000)
Very rare:	less than 0.01% (<1 / 10,000), including isolated reports
Unknown:	cannot be estimated from the available data

Gastrointestinal disorders

Rare: nausea, constipation.

Nervous system disorders

Rare: headache, dizziness, insomnia.

Not known: dizziness.

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Cardiac disorders

Rare: palpitations, hypotension

Immune system disorders

Rare: allergic reaction (local swelling of the skin, hives, rash, itchy skin).

Reporting of suspected adverse reactions

It is important to report any possible side effects after the medicine has been authorized. This allows the benefit/risk balance of the medicine to be further assessed. Healthcare professionals are asked to report any possible side effects via www.ravimiamet.ee.

5. How to store No-Spa

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

Do not store at a temperature higher than 25 °C.

Store in the original pack, protected from light.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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 No-Spa contains

- The active substance is drotaverine hydrochloride. One tablet contains 40 mg of drotaverine hydrochloride.
- The other excipients are magnesium stearate, talc, polyvidone, maize starch and lactose monohydrate.

What No-Spa looks like and contents of the pack

Yellow, round, convex tablet with a green or orange undertone, measuring 7 mm × 3.4 mm, with the writing *spa* imprinted on one side.

Packs: 20 tablets in an Alu/Alu or PVC/Alu blister; 24 tablets in a PVC/Alu blister.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Opella Healthcare France SAS

82 Avenue Raspail

94250 Gentilly

France

Manufacturer

Opella Healthcare Hungary Ltd.

(Opella Healthcare Hungary Limited Liability Company)

2112 Veresegyház

Lévai utca 5

Hungary

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

UAB „STADA Baltics“

A. Goštauto g. 40A

03163 Vilnius

Lithuania

* Clarification – 20 tbl and 24 tbl per pack – OTC medicine

100 tbl per pack – prescription medicine

Tel. +372 6011 910

This leaflet was last revised in December 2021.

Other sources of information

Detailed information on this medicine is available on the website of Agency of Medicines

<http://www.ravimiamet.ee>

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Package leaflet: Information for the user
(prescription medicine*)

No-Spa, 40 mg tablets
Drotaverine hydrochloride

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- 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 you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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Other medicines and No-Spa

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No-Spa contains lactose

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3. How to take No-Spa

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

Unless otherwise recommended by your doctor, the usual dose is:

Adults: 3 to 6 tablets orally daily in 2 to 3 divided doses.

If you take more No-Spa than you should

Based on the data available in published literature and based on reports of side effects, an overdose of drotaverine may cause weakness, malaise, dizziness, vomiting, headache, a drop in blood pressure and sleepiness. Heart rhythm and conduction disorders, incl. potentially fatal complete bundle block and cardiac arrest have also been reported.

In the case of accidental or intentional overdose, contact your doctor immediately.

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What No-Spa looks like and contents of the pack

Yellow, round, convex tablet with a green or orange undertone, measuring 7 mm × 3.4 mm, with the writing *spa* imprinted on one side.

Packs: 100 tablets in a polypropylene bottle.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Opella Healthcare France SAS
82 Avenue Raspail
94250 Gentilly
France

Manufacturer

Opella Healthcare Hungary Ltd.
(Opella Healthcare Hungary Limited Liability Company)
2112 Veresegyház
Lévai utca 5
Hungary

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