

Package leaflet: information for the user

DORALIN 40 mg film-coated tablets

Otilonium bromide

Read all of this leaflet carefully before you start taking 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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

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

1. What DORALIN is and what it is used for

DORALIN tablets contain a medicine called otilonium bromide. This belongs to a group of medicines called “spasmolytics”.

DORALIN acts on the muscles of the digestive tract, relieving bowel spasms and regulating excessive motility (e.g. by reducing the excessive bowel muscle contractions and their rate).

DORALIN is used for the treatment of **irritable bowel syndrome** and other gastrointestinal conditions characterised by painful bowel spasms, distension and motility problems in patients older than 18 years old.

2. What you need to know before you take DORALIN

Do not take DORALIN:

if you are allergic to otilonium bromide or any of the ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking DORALIN::

- if you have glaucoma (an eye disease with increased pressure in the eyeball),
- if you have an enlarged prostate gland (also known as prostatic hypertrophy),
- if you suffer from narrowing of the passage from the stomach into the intestine (pyloric stenosis).

Other medicines and DORALIN

No interactions of DORALIN with other medicines have been reported.

DORALIN with food and drink

No interaction studies of DORALIN with foods and drinks have been performed.

Take DORALIN preferably 20 minutes before meals.

Pregnancy, breast-feeding and fertility

DORALIN is not right for you if you are pregnant or breast-feeding, unless you have been told by your doctor that it is necessary and that you take it under his/her supervision.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have, ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

DORALIN is not expected to affect your ability to drive or use machines.

DORALIN contains lactose which is a type of sugar (milk sugar). 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 DORALIN

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

Adults and elderly: take 1 tablet 2 to 3 times daily, according to your doctor's advice. Take your tablets with water, preferably 20 minutes before meals, without breaking, crushing or chewing them.

Children: these tablets are not suitable for children.

If you take more DORALIN than you should

No overdose phenomena have ever been reported with DORALIN.

However, if you overdose and notice that you are not feeling well, talk to your doctor or go to the nearest hospital, taking this leaflet and/or the medicine pack with you.

If you forget to take DORALIN

If you forget to take a dose of DORALIN at the prescribed time, take it as soon as you remember. In any case, **DO NOT** take a double dose to make up for a forgotten tablet.

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

4. Possible side effects

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

DISCONTINUE the intake of tablets and seek medical advice without delay if you develop any of the below mentioned disorders that may be a sign of an **allergic reaction**:

- difficult breathing or swallowing, swelling of face, lips, tongue or throat;
- intensive skin itching with red rash and raised bumps.

Uncommon side effects (side effects that may affect up to 1 in 100 people), that you may undergo with DORALIN are:

- gastrointestinal disorders like dry mouth, nausea and abdominal pain upper;
- skin and subcutaneous tissue disorders like pruritus and erythema;
- general disorders and administration site conditions like fatigue and asthenia;
- nervous system disorders and ear and labyrinth disorders like headache and vertigo.

During post marketing experience, isolated cases of allergic skin reactions in the form of rash (urticaria) and swelling of the deeper layers of the skin, especially around the lips, eyes, genitals, hands, feet and throat or tongue, with possible sudden difficult breathing (angioedema), with unknown frequency, have been observed.

5. How to store DORALIN

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

Do not use this medicine after the expiry date which is stated on the outer carton and the blister after “Exp”. 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 to protect the environment.

Storage conditions: do not store above 30°C.

6. Contents of the pack and other information

What DORALIN contains

- The **active ingredient** is otilonium bromide (40 mg per film-coated tablet).
- **Other ingredients** are: lactose hydrate, rice starch, sodium starch glycolate, type A, magnesium stearate, hypromellose, titanium dioxide (E 171), macrogol 4000 and 6000, talc (for additional information on **lactose** see section 2).

What DORALIN looks like and contents of package

DORALIN are white to off-white, round film-coated tablets
30 film coated tablets in PVC/PVDC/Al blister, in a box.

Marketing Authorisation Holder

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Last revision of the illustrative leaflet

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