

PACKAGE LEAFLET: INFORMATION FOR THE USER

Detrunorm® 15mg film-coated tablets (propiverine hydrochloride)

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 your pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

The name of your medicine is Detrunorm 15mg film-coated tablets but will be referred to as Detrunorm throughout the remainder of this leaflet.

What is in this leaflet:

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

1. WHAT DETRUNORM IS AND WHAT IT IS USED FOR

Detrunorm is used for the treatment of people who have difficulty in controlling their bladder due to bladder overactivity or, in some cases, problems with the spinal cord. Detrunorm contains the active substance propiverine hydrochloride. This substance prevents the bladder from contracting and increases the amount that the bladder can hold. Detrunorm is used to treat the symptoms of overactive bladder.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DETRUNORM

Do not take Detrunorm

- if you are allergic (hypersensitive) to propiverine hydrochloride or to any of the other ingredients of Detrunorm (these are listed in section 6).
- if you suffer from any of the following conditions:
 - obstruction of the bowel
 - obstruction to the bladder outlet (difficulty in passing urine)
 - myasthenia gravis (a disease causing muscle weakness)
 - a loss of function of the muscles controlling your bowel movements (intestinal atony)
 - severe inflammation of the bowel (ulcerative colitis) that may lead to diarrhoea containing blood and mucus and abdominal pain
 - toxic megacolon (a condition involving enlargement of the bowel)
 - increased pressure in the eye (uncontrolled angle closure glaucoma)
 - moderate or severe liver disease
 - fast and irregular heart beat.

Warnings and precautions

Before you take Detrunorm you should tell your doctor or pharmacist if you have:

- damage to the nerves that control blood pressure, heart rate, bowel and bladder movements and other bodily functions (autonomic neuropathy)
- kidney problems
- liver problems
- severe heart failure
- enlargement of the prostate gland
- recurrent urinary tract infection
- tumours of the urinary tract
- glaucoma
- heartburn and indigestion due to back flow of gastric juice into the throat (hiatus hernia with reflux oesophagitis)
- irregular heart beat
- fast heart beat

If you suffer from any of these conditions, contact your doctor. He/she will tell you what to do. Due to its high strength Detrunorm should not be used in children younger than 12 years and adults with a body weight below 35kg.

Other medicines and Detrunorm

You should tell your doctor or pharmacist if you are taking or have taken any of the following medicines as they may interact with your Detrunorm:

- antidepressants (e.g. imipramine, clomipramine and amitriptyline)
- sleeping tablets (e.g. benzodiazepines)
- anticholinergics taken by mouth or injection (usually used to treat asthma, stomach cramps, eye problems or urinary incontinence)
- amantadine (used to treat flu and Parkinson's disease)
- neuroleptics such as promazine, olanzapine, quetiapine (drugs used to treat psychotic disorders like schizophrenia or anxiety)
- beta stimulants (drugs used to treat asthma)
- cholinergics (e.g. carbachol, pilocarpin)
- isoniazid (a treatment for tuberculosis)
- metoclopramide (used to treat nausea and vomiting)
- concomitant treatment with methimazole (used to treat hyperfunction of the thyroid gland) and medicines used to treat fungal diseases (e.g. ketoconazole, itraconazole).

Nevertheless, it may still be all right for you to take Detrunorm. Your doctor will be able to decide what is suitable for you.

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

Taking Detrunorm with food and drink

The tablets should be swallowed whole before meals.

Pregnancy, breast-feeding and fertility

Do not take Detrunorm if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

Driving and using machines

Detrunorm can sometimes cause sleepiness and blurred vision. You should not drive or operate machinery if you suffer from sleepiness and blurred vision.

Important information about some of the ingredients of Detrunorm

Detrunorm contains lactose (a sugar). If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE DETRUNORM

Always take Detrunorm exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Take your tablets at the same time each day. Swallow your tablets whole with a drink of water before meals.

Adults and the elderly:

The usual dose of Detrunorm is two or three tablets daily. You might already respond to a dose of one tablet a day.

The maximum recommended daily dose is 45mg. Due to its high dose Detrunorm should not be used in adults with a body weight below 35kg.

Children:

Detrunorm is not recommended for children.

If you take more Detrunorm than you should

If you have accidentally taken more than your prescribed dose, contact your nearest casualty department or tell your doctor or pharmacist immediately. Remember to take the pack and any remaining tablets with you.

If you forget to take Detrunorm

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

If you stop taking Detrunorm

A break or change of the dose may only be done on medical advice.

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

4. POSSIBLE SIDE EFFECTS

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

All medicines can cause allergic reactions although serious allergic reactions are very rare. The following symptoms are first signs for such reactions:

- Any sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat
- Peeling and blistering of the skin, mouth, eyes and genitals
- Rash affecting your whole body.

If you get any of these symptoms during treatment, you should contact your doctor immediately.

You might suffer an acute attack of glaucoma. In this case, you have been seeing coloured rings around lights or develop severe pain in and around either eye. You should seek medical attention immediately.

The following side effects have been reported:

Very common (may affect more than 1 in 10 people)

- dry mouth.

Common (may affect up to 1 in 10 people)

- abnormal vision and difficulty in focussing
- fatigue
- headache
- abdominal pain
- indigestion
- constipation.

Uncommon (may affect up to 1 in 100 people)

- feeling sick and vomiting
- dizziness
- trembling (tremor)
- inability to empty the bladder (urinary retention)
- flushing
- altered sense of taste
- decreased blood pressure with drowsiness
- itching
- difficulty in passing urine.

Rare (may affect up to 1 in 1,000 people)

- rash
- faster heart beat.

Very rare (may affect up to 1 in 10,000 people)

- feeling your heart beat
- restlessness and confusion.

Not known (frequency cannot be estimated from the available data)

- sensing things that are not real (hallucination)
- speech disorder.

All undesirable effects are transient and recede after a dose reduction or termination of the therapy after maximum 1-4 days.

During long-term therapy hepatic enzymes should be monitored, because reversible changes of liver enzymes might occur in rare cases.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DETRUNORM 15MG FILM-COATED TABLETS

Keep out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not use Detrunorm after the expiry date, which is stated on the blister and carton. The expiry date refers to the last day of that month.

Do not throw away any medicine 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.

If your tablets become discoloured or show any other signs of deterioration consult your pharmacist who will tell you what to do.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Detrunorm contains

The active substance is propiverine hydrochloride. Each film-coated tablet contains 15mg propiverine hydrochloride (equivalent to 13.64mg propiverine). The other ingredients are lactose monohydrate; cellulose, powdered; magnesium stearate; hypromellose; cellulose, microcrystalline; stearic acid; talc; titanium dioxide (E171).

What Detrunorm looks like and contents of the pack

Detrunorm are white, round, biconvex film-coated tablets.

Detrunorm is available in blister packs of 60 tablets.

PLPI 20774/1866 Detrunorm 15mg film-coated tablets

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This leaflet was last revised 25th August 2021

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**Blind or partially sighted?
Is this leaflet hard to see or read?
Contact Quadrant
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