PACKAGE LEAFLET: INFORMATION FOR THE USER

DETRUNORM® XL 45 MG MODIFIED RELEASE CAPSULES

(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 XL 45 mg modified-release capsules** (referred to as Detrunorm XL 45 mg throughout this leaflet). The active substance is propiverine hydrochloride and the other ingredients are listed at the end of the leaflet (section 6, Contents of the pack and other information).

What is in this leaflet:

1. WHAT DETRUNORM XL 45 MG IS AND WHAT IT IS USED FOR

Detrunorm XL 45 mg is used for the treatment of people who have difficulty in controlling their bladder due to bladder overactivity or who have problems with the spinal cord. Detrunorm XL 45 mg contains the active substance propiverine hydrochloride. This substance prevents the bladder from contracting and increases the amount that the bladder can hold. Detrunorm XL 45 mg is used to treat the symptoms of overactive bladder. It is a modified-release capsule that needs only to be taken once a day.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DETRUNORM XL 45 MG

Do not take Detrunorm XL 45 mg

Do not take Detrunorm XL 45 mg if you are allergic (hypersensitive) to propiverine hydrochloride or to any of the other ingredients of Detrunorm XL 45 mg (these are listed in section 6).
Do not take Detrunorm XL 45 mg 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 XL 45 mg you should tell your doctor 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 will tell you what to do.

Other medicines and Detrunorm XL 45 mg

You should tell your doctor if you are taking or have taken any of the following medicines as they may interact with Detrunorm XL 45 mg:
- 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 XL 45 mg. 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.

Pregnancy, breast-feeding and fertility

Do not take Detrunorm XL 45 mg if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

Driving and using machines

Detrunorm XL 45 mg can sometimes cause sleepiness and blurred vision. You should not drive or operate machinery if you suffer from sleepiness and blurred vision.

Detrunorm XL 45 mg contains lactose

Detrunorm XL 45 mg 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 XL 45 MG

Always take Detrunorm XL 45 mg exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
The recommended dose is:
Adults and the elderly: The usual dose of Detrunorm XL 45 mg is one capsule daily.

Use in children and adolescents: Detrunorm XL 45 mg is not recommended for children.

Method of administration:
Take your capsule at the same time each day. Swallow the capsule whole with a drink of water. Do not crush or chew the capsules. You may take them with or without food.

If you take more Detrunorm XL 45 mg 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 capsules with you.

If you forget to take Detrunorm XL 45 mg

Do not worry. Simply leave out that dose completely. Then take your 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 medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Detrunorm XL 45 mg 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 stop taking the capsules and 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 user in 10,000 people)
- feeling your heartbeat
- 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: http://www.hpra.ie/; E-mail: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DETRUNORM XL 45 MG

Keep out of the sight and reach of children.
Do not use Detrunorm XL 45 mg 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 store above 30°C. Store in the original package to protect the capsules from moisture.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Detrunorm XL 45 mg contains

The active substance is propiverine hydrochloride. Each modified-release capsule contains 45 mg of propiverine hydrochloride.
The other ingredients are citric acid, povidone, lactose monohydrate, talc, triethyl citrate, magnesium stearate, methacrylic acid-methyl methacrylate copolymer (1:1), methacrylic acid-methyl methacrylate copolymer (1:2), ammonio methacrylate copolymer type A, ammonio methacrylate copolymer type B, gelatine, titanium dioxide E171, red iron oxide E172, and yellow iron oxide E172.

What Detrunorm XL 45 mg looks like and contents of the pack

Detrunorm XL 45 mg capsules are orange containing white to off-white pellets.
They are available in blister packs of 14, 20, 28, 30, 49, 50, 56, 60, 84, 98, 100, 112, 168 or 280 capsules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

Consilient Health Ltd.,
5th floor, Beaux Lane House,
Mercer Street Lower, Dublin 2, Ireland

Manufacturer

APOGEPHA Arzneimittel GmbH
Kyffhäuserstraße 27
01309 Dresden
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

- Germany: Mictonorm Uno® 45 mg Hartkapseln mit veränderter Wirkstofffreisetzung
- United Kingdom: Mictonorm® XL 45 mg Modified-Release Capsules
- Ireland: Detrunorm® XL 45 mg Modified-Release Capsules
- Austria: Mictonorm® 45 mg Hartkapseln mit veränderter Wirkstofffreisetzung
- Belgium: Mictonorm® Forte 45 mg Capsule met gereguleerde afgifte
- Czech Republic: Mictonorm Uno®
- Greece: Mictonorm® Uno 45 mg Καψάκιο ελεγχόμενης αποδέσμευσης
- Italy: Mictonorm® 45 mg Capsule a rilascio modificato
- Luxembourg: Mictonorm® Forte 45 mg Gélules à libération modifiée
- Slovak Republic: Mictonorm® XL 45 mg Tvrdé kapsuly s riadeným uvoľňovaním
- Slovenia: Detrunorm® 45 mg Trde kapsule s prirejenim sproščanjem
- Portugal: Mictonorm® OD 45 mg Cápsula de libertação modificada

This leaflet was last revised in May 2021.