Package Leaflet: Information for the User

Detrunorm® XL 30 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 30 mg Modified Release Capsules (referred to as Detrunorm XL 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).
- Detrunorm XL is also available in another strength.

What is in this leaflet:

1. What Detrunorm XL is and what it is used for

Detrunorm XL is used for the treatment of people who have difficulty in controlling their bladder due to bladder overactivity. Detrunorm XL contains the active substance propiverine hydrochloride. This substance prevents the bladder from contracting and increases the amount that the bladder can hold.
Detrunorm XL 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

Do not take Detrunorm XL:
Do not take Detrunorm XL if you are allergic (hypersensitive) to propiverine hydrochloride or to any of the other ingredients of Detrunorm XL (these are listed in section 6).

Do not take Detrunorm XL 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 heartbeat

Warnings and precautions
Before you take Detrunorm XL 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 heartbeat
- fast heartbeat

If you suffer from any of these conditions, contact your doctor. He will tell you what to do.

Other medicines and Detrunorm XL
You should tell your doctor if you are taking or have taken any of the following medicines as they may interact with Detrunorm XL:
- 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, pilocarpine),
- 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. 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 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.

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

Detrunorm XL contains lactose
Detrunorm XL 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

Always take Detrunorm XL exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults and the elderly: The usual dose of Detrunorm XL is one capsule daily.

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

Method of administration:
Take your capsule at the same time each day. Swallow it with or without food or drink. Do not crush or chew the capsules.

If you take more Detrunorm XL 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
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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Detrunorm XL 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 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 the Yellow Card Scheme at: 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 XL

- **Keep out of the sight and reach of children.**
- Do not store above 25ºC.
- Store in the original package to protect from moisture.
- Do not use this medicine after the expiry date which is stated on the carton label and blister after EXP. The expiry date refers to the last day of that month.
- If your capsules become discoloured or show any sign of deterioration, return them to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Detrunorm XL contains
Each capsule contains 30 mg propiverine hydrochloride (equivalent to 27.28 mg propiverine).

The other ingredients are:
Pellets: citric acid, povidone K25, 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 and ammonio methacrylate copolymer type b.
Capsule: gelatin, titanium dioxide (E171), red iron oxide (E172) and yellow iron oxide (E172).

What Detrunorm XL looks like and contents of the pack
The capsules are orange and white and contain white to off white pellets. They are available in cartons of 28, 49 and 98 capsules.

Manufactured by
APOGEPHA Arzneimittel GmbH, Kyffhäuserstrasse 27,
01309 Dresden, Germany.

Procured from within the EU by Product Licence Holder:
MPT Pharma Ltd, Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall, WS9 8ER.

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