Package leaflet: Information for the patient
LF-117111-01

AMDIPHARM

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, 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.

The name of your medicine is **Detrunorm® XL 30 mg Modified Release Capsules** (referred to as Detrunorm throughout this leaflet).

What is in this leaflet:

1. WHAT DETRUNORM IS AND WHAT IT IS USED FOR

Detrunorm is used for the treatment of people who have difficulty in controlling their bladders due to bladder overactivity. 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. 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

Do not take Detrunorm:
- **if** you are allergic to propiverine hydrochloride or any of the other ingredients of this medicine listed in section 6 (allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing).
- if you have obstruction of the bowel;
- if you have obstruction to the bladder outlet (difficulty in passing urine);
- if you have myasthenia gravis (a disease causing muscle weakness);
- if you have a loss of function of the muscles controlling your bowel movements (intestinal atony);
- if you have severe inflammation of the bowel (ulcerative colitis) that may lead to diarrhoea containing blood and mucus and abdominal pains;
- if you have toxic megacolon (a condition involving enlargement of the bowel);
- if you have increased pressure in the eye (uncontrolled angle closure glaucoma);
- if you have moderate or severe liver disease;
- if you have fast or irregular heartbeat.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Detrunorm
- if you have damage to the nerves that control blood pressure, heart rate, bowel and bladder movement and other bodily functions (autonomic neuropathy);
- if you have liver problems;
- if you have kidney problems;
- if you have severe heart failure;
- if you have enlargement of the prostate gland;
- if you have recurrent urinary tract infection;
- if you have tumours of the urinary tract;
- if you have glaucoma;
- if you have heartburn and indigestion due to back flow of gastric juice into the throat (hiatus hernia with reflux oesophagitis);
- if you have irregular heartbeat;
- if you have fast heartbeat.

Other medicines and Detrunorm
Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines as they may interact with Detrunorm:
- antidepressants (e.g. imipramine, clomipramine,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 and anxiety);
- beta stimulants (drugs used to treat asthma);
- cholinergics (carbachol and 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, intraconazole).

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.

Pregnancy, breast-feeding and fertility
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.
Do not take Detrunorm if you are pregnant, likely to become pregnant or are breast-feeding.

Driving and using machines
Detrunorm can sometimes cause sleepiness and blurred vision. You should not drive or operate machinery until you are sure you are not affected.

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

3. HOW TO TAKE DETRUNORM

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

The recommended dosage is
Adults and the elderly: the recommended dose is one capsule daily.

Use in children and adolescents:
Detrunorm 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 than you should
If you accidentally take 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. Overdosage can cause symptoms such as restlessness, dizziness, disorders in speech and vision, muscular weakness, dry mouth, faster heartbeat and problems passing urine.

If you forget to take Detrunorm
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, pharmacist.or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine 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. If you have been seeing coloured rings around lights or if you should develop severe pain in and around either eye **you should seek medical attention urgently.**

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 (hallucinations).
Speech disorder

All possible side 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, pharmacist or nurse. 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.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DETRUNORM

Keep this medicine out of sight and reach of children
Do not store the blister pack above 30°C.
Keep the capsules in the original package to protect from moisture.
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 Detrunorm contains
The active substance is propiverine hydrochloride. Each modified release capsule contains 30 mg of propiverine hydrochloride (equivalent to 27.28 mg propiverine).
The other ingredients are citric acid, povidone, lactose monohydrate, talc, triethyl citrate, magnesium stearate, methacrylic acid-methyl methacrylate copolymer, ammonio methacrylate copolymer, gelatin, titanium dioxide (E171), red iron oxide (E172) and yellow iron oxide (E172).

What Detrunorm 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 14, 20, 28, 30, 49, 50, 56, 60, 84, 98, 100, 112 or 280 capsules.

Not all pack sizes may be marketed.

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