Package leaflet: information for the patient
200552/LF/2

AMDIPHARM

Detrunorm®15 mg 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 pharmacist.
- This leaflet provides a summary of the information available on your medicine.
- This medicine has been prescribed for you, 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 DETRUNORM 15 MG COATED TABLETS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Detrunorm 15 mg Coated Tablets (to be referred to as Detrunorm throughout the leaflet).

Detrunorm is used for the treatment of people who have difficulty in controlling their bladders 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 15 MG COATED TABLETS

Do not take Detrunorm if:

- You are allergic (hypersensitive) to propiverine hydrochloride or any of the other ingredients of Detrunorm 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).

or if you are suffering from any of the following condtions:

- 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 stomach pains;
- toxic megacolon (a condition involving enlargement of the bowel);
- increased pressure in the eye (uncontrolled angle closure glaucoma);
- moderate or severe liver disease;
- fast or irregular heartbeat.

Warnings and precautions

Take special care with this medicine if you have:

- damage to the nerves that control blood pressure, heart rate, bowel and bladder movement and other bodily functions (autonomic neuropathy);
- liver problems;
- kidney problems;
- severe heart failure;
- enlargement of the prostate gland;
- 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/she will tell you what to do.

Other medicines and Detrunorm

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

- antidepressants (e.g. imipramine, clomipramine, amitryptiline);
- 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 (e.g. drugs used to decrease the heartbeat, to stimulate the digestion and to treat glaucoma as Carbachol, Pilocarpin);
- isoniazid (a treatment for tuberculosis);
- metoclopramide (used to treat nausea and vomiting).

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 before meals.

Pregnancy and breast-feeding

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

Driving and using machinery

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

Important information about some of the ingredients of Detrunorm

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

Detrunorm Tablets also contain the colouring agent Cochineal red A (E124)
May cause allergic reactions.

3. HOW TO TAKE DETRUNORM 15 MG COATED TABLETS

Always take Detrunorm exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
The label on the carton will tell you how many tablets to take and when. Take your tablets at the same times each day. Swallow your tablets whole before meals.

Adults and the elderly: the recommended dose of Detrunorm is two to three tablets daily.
Detrunorm is not recommended for children.

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 tablets with you. Overdosage can cause symptoms such as restlessness, dizziness, vertigo, 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 missed 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 15 mg Coated Tablets 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 (affects more than 1 user in 10)
Dry mouth.

Common (affects more than 1 to 10 users in 100)
Abnormal vision and difficulty in focussing, fatigue, headache, stomach pain, indigestion, constipation.

Uncommon (affects 1 to 10 users in 1,000)
Feeling sick and vomiting, dizziness, trembling (tremor), difficulty in passing urine (urinary retention), flushing, altered sense of taste, decreased blood pressure with drowsiness.

Rare (affects 1 to 10 users in 10,000)
Rash.

Very Rare (affects less than 1 user in 10,000)
Irregular heartbeat, restlessness and confusion.

Not known (frequency cannot be estimated from the available data)
Sensing things that are not real (hallucinations).

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DETRUNORM 15 MG COATED TABLETS

Keep this medicine out of sight and reach of children

Do not store the blister pack above 25°C.
There are no special precautions for storage.
Do not use after the expiry date which is stated on the carton after EXP.
The expiry date referees to the last day of that month.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Detrunorm 15 mg Coated Tablets contain
Each tablet contains 15 mg propiverine hydrochloride (equivalent to 13.64 mg propiverine) as the active ingredient along with the following other ingredients: lactose monohydrate; powdered cellulose; magnesium stearate; sucrose; talc; heavy kaolin; calcium carbonate; titanium dioxide (E171); acacia gum; colloidal anhydrous silica; Macrogol 6000; glucose monohydrate; cochineal red A (E124, lake); Montan wax.

What Detrunorm 15 mg Coated Tablets look like and the contents of the pack
The tablets are rose-coloured sugar coated tablets. They are available in cartons of 28 or 56 tablets.

Marketing Authorisation Holder:
Amdipharm UK Limited,
Capital House,
85 King William Street,
London EC4N 7BL, UK

Manufacturer responsible for release is:
APOGEPHA Arzneimittel GmbH,
Kyffhäuserstraße 27,
01309 Dresden,
Germany

The following organisations can offer independent advice:
The Continence Foundation
307 Hatton Square
16 Baldwin's Gardens
London EC1N 7RJ
Help line Mon-Fri 9.30-4.30 Tel: 020 7831 9831

Incontact (Self help organisation for sufferers and carers)
Freepost LON12119
London NW7 1YU
Tel: 020 7530 3401

Help line Mon-Fri 9.30 am – 1.00 pm Tel. 0845 345 0165

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