Package Leaflet: Information for the User

Detrunorm® 15 mg 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® 15 mg film-coated tablets, 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 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 35 kg.

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, 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.

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

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

- **Keep out of the sight and reach of children.**
- This medicine does not require any special storage conditions.
- 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 tablets 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 contains
Each film-coated tablet contains 15 mg propiverine hydrochloride, equivalent to 13.64 mg propiverine.

The other ingredients are lactose monohydrate, powdered cellulose, magnesium stearate, hypromellose, microcrystalline cellulose, stearic acid, talc, titanium dioxide (E171).

What Detrunorm looks like and contents of the pack
White, round, biconvex, film-coated tablets with no markings on either side. They are available in cartons of 30 and 60 tablets.

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.

Repackaged by MPT Pharma Ltd.

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Amdipharm Mercury International Limited.

To request a copy of this leaflet in Braille, large print or audio please call 01922 745645 and ask for the Regulatory Department.

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

Package Leaflet: Information for the User

Propiverine Hydrochloride 15 mg film-coated tablets

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 Propiverine Hydrochloride 15 mg film-coated tablets, referred to as Propiverine Hydrochloride throughout this leaflet.

What is in this leaflet:

1. What Propiverine Hydrochloride is and what it is used for

Propiverine Hydrochloride 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. Propiverine Hydrochloride contains the active substance propiverine hydrochloride.
This substance prevents the bladder from contracting and increases the amount that the bladder can hold. Propiverine Hydrochloride is used to treat the symptoms of overactive bladder.

2. What you need to know before you take Propiverine Hydrochloride

Do not take Propiverine Hydrochloride
- if you are allergic (hypersensitive) to propiverine hydrochloride or to any of the other ingredients of Propiverine Hydrochloride (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 Propiverine Hydrochloride 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 Propiverine Hydrochloride should not be used in children younger than 12 years and adults with a body weight below 35 kg.

Other medicines and Propiverine Hydrochloride
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 Propiverine Hydrochloride:
- 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)
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- 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 Propiverine Hydrochloride. 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 Propiverine Hydrochloride with food and drink
The tablets should be swallowed whole before meals.

Pregnancy, breast-feeding and fertility
Do not take Propiverine Hydrochloride if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

Driving and using machines
Propiverine Hydrochloride 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 Propiverine Hydrochloride
Propiverine Hydrochloride 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 Propiverine Hydrochloride

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

Children:
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