

<b>Response to Clinical Committee Recommendation dated 21 September 2017</b>	
<b>APPLICANT:</b>	<b>PHARMAFRICA (PTY) LIMITED</b>
<b>PROPRIETARY NAME:</b>	<b>DETRUNORM®</b>
<b>REGISTRATION NUMBER:</b>	<b>36/5.4/0019</b>
<b>STRENGTH AND DOSAGE FORM</b>	<b>EACH TABLET CONTAINS 15 mg PROPIVERINE HYDROCHLORIDE</b>
<b>PROPOSED PATIENT INFORMATION LEAFLET</b>	

## PROPOSED PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS:

S3

### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

DETRUNORM® (Tablets). Each tablet contains 15 mg propiverine hydrochloride.

### Read all of this leaflet carefully before you start taking DETRUNORM®.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, professional healthcare provider, or your pharmacist.
- **Detrunorm** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### WHAT DETRUNORM CONTAINS

The active substance is propiverine hydrochloride.

The other ingredients are:

Lactose monohydrate, powdered cellulose, magnesium stearate, sucrose, talc, heavy kaolin, calcium carbonate, titanium dioxide (E 171), acacia gum, colloidal anhydrous silica, Macrogol 6000, glucose monohydrate, montan wax.

Contains sugar – lactose monohydrate; glucose and sucrose.

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### WHAT DETRUNORM IS USED FOR

Detrunorm is used to treat people who have difficulty controlling their

bladder (incontinence) 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.

Detrunorm can, in some cases be used for people who have an over active bladder because of spinal injuries.

### BEFORE YOU TAKE DETRUNORM

#### Do not take Detrunorm:

- if you're allergic (*hypersensitive*) to propiverine, or to any of the other ingredients of **Detrunorm**.
- if you are pregnant or breastfeeding.
- or if you are suffering from any of the following conditions:
  - bowel obstruction
  - severe inflammation of the bowel (ulcerative colitis) that may lead to diarrhoea containing blood and mucus and stomach pain
  - bladder obstruction, causing difficulty in passing urine;
  - a loss of function of the muscles controlling your bowel movements (intestinal atony);
  - muscle weakness (myasthenia gravis);
  - toxic megacolon (a condition involving enlargement of the bowel, fever, pain and tenderness of the abdomen)
  - increased pressure in the eye (uncontrolled angle closure glaucoma);
  - moderate or severe liver disease

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- fast or irregular heart beat (tachyarrhythmia).

**Special care should be taken if** you have:

- damage to the nerves which supply the internal organs (autonomic neuropathy);
- severe heart failure, or a fast or irregular heart beat;
- an enlarged prostate gland
- heartburn and indigestion due to a back flow of acid into the food pipe (hiatus hernia with reflux oesophagitis);
- liver or kidneys problems.

Tell your doctor before taking this medicine if you have been told you have an intolerance to some sugars.

This is because Detrunorm contain lactose, glucose and sucrose (types of sugars).

**Taking Detrunorm with food and drink:**

Detrunorm should be taken before meals.

**Driving and using machinery:**

Detrunorm may cause drowsiness and blurred vision.

You should not drive or operate machinery until you are sure you are not affected.

**Taking other medicines with Detrunorm:**

**Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)**

The following types of medicines may increase the effects of Detrunorm:

- medicines to treat problems, such as depression (e.g.

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imipramine, clomipramine and amitryptiline); anxiety or

psychosis (e.g. neuroleptics such as promazine, olanzapine, quetiapine) or sleep difficulties;

- medicines belonging to a class known as sympathomimetics (these are used to treat a range of conditions; including asthma and heart conditions);
- medicines belonging to a class known as anticholinergics (these are used to treat a range of conditions, including asthma, stomach cramps, eye problems, urinary incontinence);
- amantadine (used to treat flu or Parkinson's disease)

The effects of following types of medicines may be decrease if taken with Detrunorm:

- medicines to treat stomach problems or nausea and vomiting (e.g. metoclopramide)

The following types of medicines may decrease the effects of Detrunorm:

- Medicines belonging to the class of cholinergics (e.g. carbachol, pilocarpine)

Isoniazid (used to treat tuberculosis) if taken together with Detrunorm can lead to reduced blood pressure

## HOW TO TAKE DETRUNORM

**Do not share medicines prescribed for you with any other person.**

**Always take Detrunorm exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are unsure.**

As a standard dose one coated tablet (= 15 mg propiverine hydrochloride) two times a day is recommended, this may be increased to three times a day.

Some patients may respond to a dosage of 15 mg a day.

The maximum recommended daily dose is 45 mg.

For neurogenic detrusor overactivity a dose of one coated tablet three times daily is recommended.

Elderly:

Generally there is no special dosage regimen for the elderly.

Detrunorm is not recommended for children.

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Your doctor will tell you how long your treatment with Detrunorm will last. If you have the impression that the effect of Detrunorm is too strong or too weak, tell your doctor or pharmacist.

**If you take more Detrunorm than you should:**

In the event of an overdosage consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.

**If you forget to take Detrunorm:**

Don't take extra tablets to make up for a missed dose. Just take your next dose at the usual time.

**If you want to stop Detrunorm:**

Don't stop taking **Detrunorm** without talking to your doctor first.

If you have any further questions on the use of this product, ask your doctor, pharmacist or healthcare professional.

**POSSIBLE SIDE EFFECTS**

**Detrunorm** can have side effects.

**Note: Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.**

If any of the following happens stop taking Detrunorm and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Any sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or

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throat.

- Peeling and blistering of the skin, mouth, eyes and genitals
- Rash affecting your whole body.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Detrunorm. You may need urgent medical attention or hospitalisation.

It is possible that 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.

Tell your doctor if you notice any of the following:

Frequent Side Effects

Dryness of the mouth.

Constipation, abnormal vision and difficulty in focussing, fatigue, headache, abdominal pain, indigestion.

Less Frequent Side Effects

Decreased blood pressure (with drowsiness), problems passing urine, flushing of the face and neck, shaking, dizziness, nausea and vomiting, altered sense of taste.

Hypersensitivity, rash or irritation

Irregular heartbeats, confusion or restlessness.

Frequency unknown:

Sensing things that are not real (hallucination)

These side effects will pass and will stop altogether within 1 to 4 days after having your dose reduced, or if you stop taking the tablets.

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If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **STORING AND DISPOSING OF DETRUNORM**

STORE ALL MEDICINE OUT OF THE REACH OF CHILDREN.

Store at or below 30 °C. Store in the original package.

Do not use after the expiry date printed on the pack.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Return all unused medicine to you pharmacist.

#### **PRESENTATION OF DETRUNORM**

Strips (Alu-PVC blister foil) in carton with 10 sugar-coated tablets per strip:

30 Tablets (3 strips per carton)

#### **IDENTIFICATION OF DETRUNORM**

White biconvex round coated tablets of uniform external appearance.

#### **REGISTRATION NUMBER**

36/5.4/0019

#### **NAME AND ADDRESS OF THE HOLDER OF THE REGISTRATION CERTIFICATE**

Litha Pharma (Pty) Ltd

No. 106, 16th Road,

Midrand, 1686,

Gauteng,

South Africa

Under license from APOGEPHA Arzneimittel GmbH

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#### **DATE OF PUBLICATION**

Date on the registration certificate of the medicine:

15 November 2002

Date of the most recently revised Patient Information Leaflet as approved

by Council:

To be determined.

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