PATIENT INFORMATION LEAFLET: DETRUNORM® XL

Scheduling status

S3

Proprietary name and dosage form

DETRUNORM® XL (Modified release Capsules)

Read all of this leaflet carefully before you start taking DETRUNORM® XL Capsules

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

DETRUNORM® XL 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® XL CONTAINS:

Each capsule contains 30 mg propiverine hydrochloride as the active ingredient. The other ingredients are : citric acid (anhydrous), povidone, lactose monohydrate, talc, triethyl citrate, magnesium stearate, methacrylic-acid methyl methacrylate copolymer (1: 1), (Eudragit L®) and methacrylic acid – methyl methacrylate copolymer (1:2), (Eudragit S®), ammonio methacrylate copolymer type A (Eudragit RL®) and ammonio methacrylate copolymer type B (Eudragit RS®), gelatin. Titanium dioxide E171, Red iron oxide E 172, Yellow iron oxide E 172

Contains sugar – lactose monohydrate.

WHAT DETRUNORM® XL IS USED FOR

DETRUNORM XL® is used to treat people who have difficulty in controlling bladder overactivity.

BEFORE YOU TAKE DETRUNORM® XL

If you are taking medicines on a regular basis, concomitant use of** DETRUNORM® XL **may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

Do not take DETRUNORM® XL

- If you are hypersensitive (allergic) to the propiverine hydrochloride or any of the other ingredients contained in **DETRUNORM®XL**.
- If you are suffering from any of the following conditions :

  obstruction of the bowel

  obstruction of the bladder, causing difficulty in passing urine

  myasthenia gravis (a muscle weakness)

  a loss of function of the muscles controlling your bowel movements

  severe ulceration of the bowel (ulcerative colitis) that may lead to diarrhoea containing blood and mucus and stomach pains.

  toxic megacolon (fever, pain and tenderness of the abdomen)

  increased pressure in the eye (glaucoma)

  Liver or kidney disease

  fast and irregular heart beat

  if you are pregnant or breastfeeding (see pregnancy and breastfeeding)

  not to be used in children

Take special care with **DETRUNORM® XL** if you have

- paralysis of part of the nervous system
- heart failure, fast or irregular beat
- enlargement of the prostate gland
- hiatus hernia with reflux oesophagitis (heartburn and indigestion due to backflow of acid into the food pipe)

- **DETRUNORM® XL** with other medicines that have a sedating effect as there may be an increase in sedation.

Pregnancy and Breastfeeding

DETRUNORM® XL is contra-indicated during pregnancy and breastfeeding.
If you are pregnant or breastfeeding your baby while taking **DETRUNORM® XL** please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery while taking DETRUNORM®XL:

DETRUNORM® XL capsules can cause drowsiness and blurred vision. You should not drive or operate machinery until you know how **DETRUNORM® XL** affects you

Important information about some of the ingredients of DETRUNORM® XL

DETRUNORM ®XL contains lactose and should be used with caution if you are lactose-intolerant.

Taking other medicines with DETRUNORM® XL

Some medicines may interact with **DETRUNORM® XL**. Ask your doctor to verify that it is alright to take **DETRUNORM® XL**. Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
Taking **DETRUNORM® XL** with medicines that have a sedative effect may result in an increase in sedation. Please consult your doctor, pharmacist or other healthcare professional for advice.

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 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)

neuroleptics such as promazine, olanzapine, quetiapine (medicines used to treat psychotic disorders like schizophrenia or anxiety),

beta stimulants (medicines used to treat asthma),

isoniazid (to treat tuberculosis) and

metoclopramide (used to treat nausea and vomiting)

HOW TO TAKE DETRUNORM® XL

Always take **DETRUNORM® XL** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. The usual dose is one capsule to be swallowed once a day.

If you have the impression that the effect of **DETRUNORM® XL** is too strong or too weak, talk to your doctor or pharmacist.

Do not chew.

If you take more DETRUNORM® XL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

The following symptoms may be experienced in the case of an overdose:

Restlessness, dizziness, muscular weakness, disorders in speech and vision, dryness of mucosa, cardiovascular disorders such as irregular heartbeat.

If you forget to take DETRUNORM® XL

If you forget to take your **DETRUNORM® XL** take the missed dose as soon as you remember and then carry on with your regular dosing schedule. DO NOT TAKE A DOUBLE DOSE to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS

DETRUNORM® XL can have side effects.

DETRUNORM® XL 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.

The following side effects have also been reported:

Frequent:

dry mouth

abnormal vision and difficulty in focussing

fatigue

headache

stomach pain

indigestion

constipation

Less frequent:

feeling sick and vomiting

dizziness

trembling (tremor)

difficulty in passing urine (urinary retention)

flushing

altered sense of taste

decreased blood pressure with drowsiness

rash

irregular heartbeat

restlessness and confusion.

sensing things that are not real (hallucination)

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

Not all side-effects reported for DETRUNORM® XL are included in this leaflet. Should your general health worsen while taking DETRUNORM® XL, please consult your doctor, pharmacist or other health care professional for advice.

STORING AND DISPOSING OF DETRUNORM® XL

Store at or below 30 °C.

Keep out of reach of children

PRESENTATION OF DETRUNORM® XL

Strips (Alu-PVC blister foil) in carton with 7 capsules per strip:

14, 21, 28, 35, 42 or 70 Capsules (2/3/4/5/6 or 10 strips per carton)

IDENTIFICATION OF DETRUNORM® XL

Non-transparent orange cap, non-transparent white body, contents of capsule shall be white or almost white pellets.

REGISTRATION NUMBER

A40/5.4/0439

NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER

Litha Pharma (Pty) Ltd

106 16th Road

Midrand

1685

South Africa

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