PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

DETRUNORM® PAED 5 mg Tablets.

Each tablet contains 5 mg propiverine hydrochloride.

Contains lactose monohydrate (34 mg), glucose monohydrate (0,31 mg) and sucrose (24,5 mg)

Read all of this leaflet carefully before you/your child start taking

DETRUNORM® PAED

- 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® PAED has been prescribed for you/ your child personally and you should not share your/your child's medicine with other people. It may harm them, even if their symptoms are the same as yours or your child's.

What is in this leaflet

1. What DETRUNORM® PAED is and what it is used for
2. What you need to know before you take/give DETRUNORM® PAED
3. How to take/give DETRUNORM® PAED
4. Possible side effects
5. How to store DETRUNORM® PAED
6. Contents of the pack and other information

1. What DETRUNORM® PAED is and what it used for

DETRUNORM® PAED is used to treat people (adults or children) who have difficulty controlling their bladder (incontinence). It reduces the contraction of the bladder and helps to increase how much urine it can hold.

DETRUNORM® PAED can, in some cases be used for people who have an overactive bladder because of spinal injuries.

2. What you need to know before you take/ give DETRUNORM® PAED

Do not take/give DETRUNORM® PAED:

- if you or your child is allergic *(hypersensitive)* to propiverine hydrochloride, or to any of the other ingredients of DETRUNORM® PAED listed in section 6.
- if you or your child suffer 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 abdominal 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;
  - fast and irregular heartbeat (tachyarrhythmia).

Warnings and precautions

Special care should be taken with DETRUNORM® PAED if you/ your child have:

- damage to the nerves that control blood pressure, heart rate, bowel and bladder movement and other bodily functions (autonomic neuropathy);
- severe heart failure, or a fast or irregular heartbeat;
- an enlarged prostate gland (men only);

- heartburn and indigestion due to a back flow of acid into the food pipe (hiatus hernia with reflux oesophagitis);
- liver or kidney problems.
- recurrent urinary tract infection
- tumours of the urinary tract
- glaucoma

If you or your child suffer from any of these conditions, contact your doctor. He will tell you what to do.

Children

The treatment of children with symptoms of overactive bladder should not begin before an age of 5 years and is only recommended in addition with behavior modification, like voiding and drinking habits.

The treatment of children with spinal cord injuries may be started before an age of 5 years.

The treatment of children younger than 1 year is not recommended due to a lack of data.

Other medicines and DETRUNORM® PAED*:*

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

The following types of medicines may increase the effects of DETRUNORM® PAED:

- medicines to treat problems, such as depression (e.g. imipramine, clomipramine and amitryptiline), anxiety or psychosis (e.g. neuroleptics such as promazine, olanzapine, quetiapine) or sleep difficulties (e.g. benzodiazepines);
- 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).
- concomitant treatment with methimazole (used to treat hyperfunction of the thyroid gland) and medicines used to treat fungal diseases (e.g. ketoconazole, itraconazole)

The effects of following types of medicines may decrease if taken with DETRUNORM® PAED:

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

The following types of medicines may decrease the effects of DETRUNORM® PAED:

- medicines belonging to the class of cholinergics (e.g. carbachol, pilocarpin)
- isoniazid (used to treat tuberculosis) if taken together with DETRUNORM® PAED can lead to reduced blood pressure.

DETRUNORM® PAED with food and drink:

There are no known food and/or drink interactions with DETRUNORM® PAED.

Pregnancy and breastfeeding

If you are pregnant, think you may be pregnant or are planning to have a baby or are breastfeeding you should not take DETRUNORM® PAED**.**

Driving and using machinery:

DETRUNORM® PAED can sometimes cause drowsiness and blurred vision. It is not always possible to predict to what extent DETRUNORM® PAED may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DETRUNORM® PAED affects them.

DETRUNORM® PAED contains lactose monohydrate; glucose monohydrate and sucrose which may have an effect on the control of your / your child's blood sugar if you/ your child has diabetes mellitus.

Patients with the rare hereditary conditions of lactose or galactose intolerance should not take DETRUNORM® PAED.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking DETRUNORM® PAED.

3. How to take/give DETRUNORM® PAED

Do not share medicines prescribed for you or your child with any other person.

Always take or give your child DETRUNORM® PAED exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are unsure.

Children:

The recommended dose is two or three doses with an average daily dose of 0.8 mg/kg body weight per day. Possible dosage schedules:

Body weight (kg)	DETRUNORM® PAED 5 mg
12-16	1-0-1
17-22	1-1-1
23-28	2-0-2
29-34	2-1-2
≥35	2-2-2 or
	3-0-3

In children or adolescents with a body weight over 35 kg the maximum dose is the same as the standard adult dosage of 15 mg twice daily (2 x 3 DETRUNORM® PAED).

Adults and the elderly:

As a standard dose for overactive bladder, 15 mg propiverine hydrochloride twice daily is recommended; an increase to three times daily is possible. Some patients may respond to a dose as low as 15 mg daily (3 x 5 mg).

For neurogenic detrusor overactivity, a dosage of 15 mg propiverine hydrochloride three times daily is recommended. The maximum recommended daily dose is 45 mg.

DETRUNORM® PAED should be taken before meals. Take your tablets at the same times each day. The tablets should be swallowed whole with water.

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

If you take more or if your child has been given more DETRUNORM® PAED than you/ your child should:

In the event of an overdosage consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre. Remember to take the pack and any remaining tablets with you.

If you forget to take/ give DETRUNORM® PAED:

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

If you want to stop DETRUNORM® PAED:

Don't stop taking/ giving **DETRUNORM® PAED** 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.

4. Possible side effects

DETRUNORM® PAED can have side effects.

Not all side effects reported for this medicine are included in this leaflet. Should you/your child's general health worsen or if you/your child 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/ giving **DETRUNORM® PAED** 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 throat
- Peeling and blistering of the skin, mouth, eyes or genitals
- Rash affecting your whole body.

These are all very serious side effects. If you/ your child have them, you/ your child may have had a serious allergic reaction to DETRUNORM® PAED.

You/ your child may need urgent medical attention or hospitalisation.

It is possible that you/your child might suffer an acute attack of glaucoma:

- If you have been seeing coloured rings around lights or if you or your child 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, inability to empty the bladder, itching.
- Rash or irritation, faster heartbeat.
- Feeling your heart beat, confusion or restlessness.
- Trembling (tremor)

Frequency unknown:

- Sensing things that are not real (hallucination), speech disorder

Additional side effects in children and adolescents

In addition, in clinical studies with children the following undesirable effects were observed: loss of appetite, sleep disturbance and impaired concentration.

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

During long-term therapy hepatic enzymes should be monitored, because reversible changes of liver enzymes might occur in rare cases.

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.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of DETRUNORM® PAED.

5. How to store DETRUNORM® PAED

Store all medicines out of reach of children.

Store at or below 25 °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.

6. Contents of the pack and other information

What DETRUNORM® PAED 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.

What DETRUNORM® PAED looks like and contents of the pack

White, lenticular coated tablets.

Blister foil strips packed in an outer carton with 14 tablets per strip: Pack size: 28 tablets (2 strips per carton).

Holder of Certificate of Registration

Acino Pharma (Pty) Ltd

No. 106, 16th Road,

Midrand, 1686,

Gauteng,

South Africa

Under license from APOGEPHA Arzneimittel GmbH

This leaflet was last revised in

19 July 2022

Registration number

49/5.4/0967

Access to the corresponding Professional Information

TBC