Mictonorm® 15 mg Film-coated tablets

(propiverine hydrochloride)

Your medicine is known by the above name, but will be referred to as Mictonorm throughout this leaflet.

Patient Information Leaflet

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 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).

What is in this leaflet:

1) What Mictonorm are and what it is used for

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

2) What you need to know before you take Mictonorm

Do not take Mictonorm

Do not take Mictonorm if you are allergic (hypersensitive) to propiverine hydrochloride or to any of the other ingredients of Mictonorm (these are listed in section 6).

Do not take Mictonorm 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 Mictonorm you should tell your doctor 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 will tell you what to do.

Other medicines and Mictonorm

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

- 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, itraconazole).

Nevertheless, it may still be all right for you to take Mictonorm. 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 Mictonorm with food and drink

The tablets should be swallowed whole before meals.

Pregnancy, breast-feeding and fertility

Do not take Mictonorm if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

Driving and using machines

Mictonorm can sometimes cause sleepiness and blurred vision. You should not drive or operate machinery if you suffer from sleepiness and blurred vision.

Mictonorm contains lactose

Mictonorm 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 Mictonorm

Always take Mictonorm exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults and the elderly: The usual dose of Mictonorm is two or three film-coated tablets daily. You might already respond to a dose of one tablet a day. The maximum recommended daily dose is 45 mg.

Use in children and adolescents: Mictonorm is not recommended for children.

Method of administration:

Take your tablets at the same times each day. Swallow your tablets whole with a drink of water before meals.

If you take more Mictonorm 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 Mictonorm

Do not worry. Take your recommended dose as soon as you remember, unless it is nearly time for the next dose. Then take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

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

4) Possible side effects

Like all medicines, Mictonorm 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 tablets and 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 at: 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 Mictonorm

- **Keep out of the sight and reach of children.**
- This medicine does not require any special storage conditions.
- Do not use Mictonorm after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.
- If the medicine becomes discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6) Contents of the pack and other information

What Mictonorm contains
The active substance is propiverine hydrochloride. 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 Mictonorm looks like and contents of the pack
Mictonorm 15 mg film-coated tablets are white, biconvex, round, film-coated tablets.
They are available in blister packs 56 tablets.

PL 46420/0516 Mictonorm 15 mg Film-coated tablets **POM**

Who makes and repackages your medicine?
Your medicine is manufactured by Apogepha Arzneimittel GmbH, Kyffhäuserstraße 27, 01309 Dresden, Germany. Procured from within the EU by the Product Licence Holder: Necessity Supplies Limited, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS and repackaged by Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

Leaflet date: 08.06.2023

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Propiverine hydrochloride 15 mg Film-coated tablets

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What is in this leaflet:

1) What Propiverine hydrochloride tablets are and what they are used for

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

2) What you need to know before you take Propiverine hydrochloride tablets

Do not take Propiverine hydrochloride tablets

Do not take Propiverine hydrochloride tablets if you are allergic (hypersensitive) to propiverine hydrochloride or to any of the other ingredients of Propiverine hydrochloride tablets (these are listed in section 6).

Do not take Propiverine hydrochloride tablets 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 tablets you should tell your doctor 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
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