

Mictonorm[®] Film Coated Tablets

Propiverine HCl (15mg)

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What Mictonorm[®] Film Coated Tablets is used for

Mictonorm[®] Film Coated Tablets is used for the treatment of people who have difficulty in controlling their bladders due to bladder overactivity or, in some cases, problems with the spinal cord. Mictonorm[®] Film Coated Tablets is used to treat the symptoms of overactive bladder.

How Mictonorm[®] Film Coated Tablets works

Mictonorm[®] Film Coated Tablets contains the active substance propiverine hydrochloride. This substance prevents the bladder from contracting and increases the amount that the bladder can hold.

Before you use Mictonorm[®] Film Coated Tablets

- When you must not use it
Do not take Mictonorm[®] if you are allergic (hypersensitive) to propiverine hydrochloride or to any of the other ingredients of Mictonorm[®] Film Coated Tablets (these are listed in Product Description).

Do not take Mictonorm[®] Film Coated 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 stomach pains
- 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 heartbeat

Do not take Mictonorm[®] Film Coated Tablets if you are pregnant, likely to become pregnant or are breast-feeding.

- Before you start use it

Before you take Mictonorm[®] Film Coated 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
- 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.

- Taking other medicines

You should tell your doctor if you are taking or have taken any of the following medicines as they may interact with your Mictonorm[®] Film Coated Tablets

- 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),
- neuroleptics such as promazine, olanzapine, quetiapine (drugs used to treat psychotic disorders like schizophrenia or anxiety),
- beta stimulants (drugs used to treat asthma),
- isoniazid (a treatment for tuberculosis) and
- metoclopramide (used to treat nausea and vomiting).

Nevertheless, it may still be alright for you to take Mictonorm[®] Film Coated Tablets. 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.

How to use Mictonorm[®] Film Coated Tablets

- How much to use

Adults and the elderly: The usual dose of Mictonorm[®] Film Coated Tablets is two or three tablets daily.

Mictonorm[®] Film Coated Tablets is not recommended for children.

Renal impairment: maximum daily dose is 30mg

- When to use it

The tablets should be swallowed whole before meals. Take your tablets at the same times each day.

- How long to use it

Always take Mictonorm[®] Film Coated Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- If you forget to use it

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 missed dose.

- If you use too much (overdose)

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.

While you are using it**- Things you must do**

Tell any other doctors, dentists or pharmacists who are treating you that you are taking Mictonorm® Film Coated Tablets.

- Things you must not do

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

- Things to be careful of

Mictonorm® Film Coated Tablets contains lactose (sugars). If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

Side effects

Like all medicines, Mictonorm® Film Coated Tablets 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. In theory, you might suffer an acute attack of glaucoma. In this case, you have been seeing colored rings around lights or develop severe pain in and around either eye. You should seek medical attention immediately.

The following side effects have also been reported:

- dry mouth
- abnormal vision and difficulty in focusing
- fatigue
- headache
- stomach pain
- indigestion
- constipation
- 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Mictonorm® Film Coated Tablets**- Storage**

Keep Mictonorm® Film Coated Tablets out of the reach and sight of children.

Store below 30°C.

Do not use Mictonorm® Film Coated Tablets after the expiry date, which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

- Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Product Description**- What it looks like**

Mictonorm® Film coated tablets are white, round, biconvex film-coated tablet of uniform external appearance.

They are available in cartons of 28 or 56 tablets.

Not all pack sizes may be marketed.

- Ingredients**- Active ingredient**

Each tablet contains 15mg of propiverine hydrochloride

- Inactive ingredients

Powdered cellulose, magnesium stearate, lactose monohydrate, Hypromellose, cellulose microcrystalline, stearic acid, talc, titanium dioxide.

- MAL number:

MAL XXXXXX

Manufacturer

ROTTENDORF PHARMA GMBH
OSTENFELDER STR. 51-61, D-59320
ENNIGERLOH GERMANY

Product Registration Holder

Pharmaforte(M) Sdn Bhd
2, Jalan PJU 3/49,
Sunway Damansara,

47810 Petaling Jaya,
Selangor.

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