

Mictonorm[®] XL 30 mg Modified Release Capsules

(Propiverine hydrochloride)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

The name of your medicine is Mictonorm XL 30 mg Modified Release Capsules (referred to as Mictonorm XL throughout this leaflet). The active substance is propiverine hydrochloride and the other ingredients are listed at the end of the leaflet (Section 6. Further Information).

In this leaflet:

1. What Mictonorm XL is and what it is used for.
2. Before you take Mictonorm XL.
3. How to take Mictonorm XL.
4. Possible side effects.
5. How to store Mictonorm XL.
6. Further information.

1. WHAT MICTONORM XL IS AND WHAT IT IS USED FOR

Mictonorm XL is used for the treatment of people who have difficulty in controlling their bladders due to bladder overactivity. Mictonorm XL contains the active substance propiverine hydrochloride. This substance prevents the bladder from

contracting and increases the amount that the bladder can hold. Mictonorm XL is used to treat the symptoms of overactive bladder. It is a modified-release capsule that needs only be taken once a day.

2. BEFORE YOU TAKE MICTONORM XL

DO NOT take Mictonorm XL if:

- Do not take Mictonorm XL if you are allergic (hypersensitive) to propiverine hydrochloride or to any of the other ingredients of Mictonorm XL (these are listed in section 6, Further information)
- Do not take Mictonorm XL 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
 - moderate or severe liver disease
 - fast and irregular heart beat
 - you are pregnant or breast-feeding

Take special care with Mictonorm XL

Before you take Mictonorm XL 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)
- severe kidney problems
- moderate or severe 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.

3. HOW TO TAKE MICTONORM XL

Always take Mictonorm XL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The label on the carton will tell you how many capsules you should take and when. Take your capsule at the same time each day. Swallow it with or without food or drink. Do not crush or chew the capsules.

Adults and the elderly: The usual dose of Mictonorm XL is one capsule daily.

Mictonorm XL is not recommended for children.

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 Mictonorm XL:

- 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 all right for you to take Mictonorm XL. 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 XL with food and drink

The capsules should be swallowed with or without food or drink.

Pregnancy and breast-feeding

Do not take Mictonorm XL if you are pregnant, likely to become pregnant or are breast-feeding.

Driving and using machines

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

Important information about some of the ingredients of Mictonorm XL

Mictonorm XL 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.

If you take more Mictonorm XL 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 capsules with you.

If you forget to take Mictonorm XL

Do not worry. Simply leave out that dose completely. Then take your next dose at the right time. Do not take a double dose to make up for a missed dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Mictonorm XL 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 coloured 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:

Very common side effects (affecting more than 1 in 10 people)

- dry mouth

Common side effects (affecting up to 1 in 10 people)

- abnormal vision and difficulty in focussing
- fatigue
- headache
- stomach pain
- indigestion
- constipation

Uncommon side effects (affecting fewer than 1 in 100 people)

- feeling sick and vomiting
- dizziness
- trembling (tremor)
- difficulty in passing urine (urinary retention)
- flushing
- altered sense of taste
- decreased blood pressure with drowsiness

Rare side effects (affecting fewer than 1 in 1,000 people)

- rash

Very rare side effects (affecting fewer than 1 in 10,000 people)

- irregular heartbeat
- restlessness and confusion.

Frequency is not known (cannot be estimated from the available data)

- 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.

5. HOW TO STORE MICTONORM XL

Keep Mictonorm XL out of the reach and sight of children.

Do not store your capsules above 25 °C. Store in the original package to protect the capsules from light and moisture.

Do not use Mictonorm XL after the expiry date, which is stated on the blister or bottle and carton after EXP. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION

What Mictonorm XL contains:

- The active substance is propiverine hydrochloride. Each capsule contains 30 mg of modified release propiverine hydrochloride
- The other ingredients are citric acid, povidone, lactose monohydrate, talc, triethyl citrate, magnesium stearate, methacrylic acid-methyl methacrylate copolymer, methacrylic acid-methyl methacrylate copolymer, ammonio methacrylate copolymer type A, ammonio methacrylate copolymer type B, gelatine, titanium dioxide E171, red iron oxide E172, and yellow iron oxide E172.

What Mictonorm XL looks like and the contents of the pack:

Mictonorm XL capsules are orange and white containing white to off-white pellets.

They are available in

- cartons of 14, 20, 28, 30, 49, 50, 56, 60, 84, 98, 100, 112 or 280 capsules.
- bottles of 10, 14, 20, 28, 30, 49, 50, 56, 60, 84, 98 or 100 capsules.

The polyethylene bottles with a polypropylene screw cap contain a silica gel desiccant.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

APOGEPHA Arzneimittel GmbH
Kyffhäuserstraße 27
01309 Dresden
Germany

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