Mictonorm®

Package Leaflet
Read *all this leaflet carefully* before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

Mictonorm®

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, montan wax.

Marketing authorisation holder:
APOGEPHA Arzneimittel GmbH, Kyffhaeuserstrasse 27, 01309 Dresden, Germany

1. WHAT Mictonorm® IS AND WHAT IT IS USED FOR

Mictonorm® belongs to a group of medicines called anticholinergics. They increase the capacity of the bladder by interfering with the process that causes the bladder to contract.

Each coated tablet contains 15 mg of propiverine hydrochloride equivalent of 13.64 mg propiverine.

Mictonorm® is available in packages with 28 coated tablets.

Mictonorm® is used to treat urinary incontinence (wetting accidents), as well as urgency (a strong need to urinate) and frequency (urinating often) in patients who have detrusor overactivity (overactive bladder, involuntary contractions of the bladder). The overactivity can be caused by spinal cord injuries, e.g. transverse lesion paraplegia (neurogenic detrusor overactivity, detrusor hyperreflexia) or by other reasons (idiopathic detrusor overactivity).

2. BEFORE YOU TAKE Mictonorm®

Do not take Mictonorm®:
- If you are hypersensitive to propiverine hydrochloride or to any of the other ingredients of Mictonorm®
- If you suffer from any of the following disorders:
  - obstruction of the bowel
  - significant degree of bladder outflow obstruction where urinary retention my be anticipated
  - myasthenia gravis (a muscle weakness)
  - intestinal alony (inactivity)
  - *severe ulcerative colitis*
  - toxic megacolon (fever, pain and tenderness of the abdomen)
  - uncontrolled angle closure glaucoma
  - significantly reduced hepatic function
  - tachyarrhythmias (fast and irregular heartbeat).

Take special care with Mictonorm®:
- If you suffer from autonomic neuropathy

Symptoms of the following diseases may be aggravated following administration of the drug:
- severe congestive heart failure (NYHA IV)
- prostatic hypertrophy (enlargement of the prostate gland)
- hiatus hernia with reflux oesophagitis (heartburn and indigestion due to back flow of acid into the food pipe).

Pollakiuria (urinating often) and nocturia (urinating at night) due to diseases of the kidney of congestive heart failure as well as organic bladder diseases (e.g. urinary tract infections, malignancy) should be ruled out prior to treatment.

Please contact your doctor, even if these statements were applicable to you at any time in the past.

Due to lack data Mictonorm® should not be used in children.

Pregnancy and breast feeding
Avoid use in pregnancy & nursing mothers.

Driving and using machines
Propiverine hydrochloride can sometimes cause drowsiness and blurred vision. You should not drive or operate machinery until you are sure you are not affected.

Sedative drugs may enhance the drowsiness caused by propiverine hydrochloride.

Important information about some of the ingredients of Mictonorm®
Each coated tablet contains 0.61 mg of glucose and a daily dose of 2 coated tablets supplies 1.22 mg of glucose.

Using other medicines
Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Increased effects of propiverine hydrochloride due to concomitant medication with tricyclic antidepressant (e.g. imipramine), tranquillisers (e.g. benzodiazepines), anticholinergics (if applied systemically), amantadine, neuroleptics (e.g. phenothiazines) and beta-adrenoceptor agonists (beta-sympathomimetics).

Decreased effects of propiverine hydrochloride due to concomitant medication with cholinergic drugs. Reduced blood pressure in patients treated with isoniazid. The effect of prokinetics such as metoclopramide may be decreased.

Propiverine hydrochloride may slightly reduce the activity of drug metabolizing enzymes (CYP3A4). This effect is small compared to well known enzyme inhibitors (e.g. ketoconazole) or grapefruit juice.

For details ask your physician.

3. HOW TO TAKE Mictonorm®

Always take Mictonorm® exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. The usual dose for adults is:
- One coated tablet two times a day (30 mg propiverine hydrochloride). This may be increased to three times a day (45 mg propiverine hydrochloride). Some patients may already respond to one coated tablet a day (15 mg propiverine hydrochloride).
- For neurogenic detrusor overavtivity one coated tablet three times a day (45 mg propiverine hydrochloride) is recommended. This may be increased to one coated tablet four times a day (60 mg propiverine hydrochloride) if required and tolerated.

Take the coated tablets at regular intervals with a glass of water, before or after the meal.

Generally three is no special dosage regimen for the elderly.

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

If you take more Mictonorm® than you should:
If any of the following happen, stop taking Mictonorm® and tell your doctor immediately:
- central anticholinergic effects, e.g. restlessness, dizziness, vertigo disorders in speech and vision, muscular weakness;
- severe dryness of mucosa;
- tachycardia;
- urinary retention.

Treatment should be symptomatic and supportive. Management of overdose may include initiation of vomiting or gastric lavage using an oiled tube (attention: dryness of mucosa!).

If you forget to take Mictonorm®:
Take your recommended dose as soon as you remember, then carry on as before. Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Mictonorm® can have side effects.

The estimated frequency is currently subdivided:
- Very common (more than 1 per 10)
- Common (less than 1 per 10 but more than 1 per 100)
- Uncommon (less than 1 per 100 but more than 1 per 1,000)
- Rare (less than 1 per 1,000 but more than 1 per 10,000)
- Very rare (less than 1 per 10,000, including isolated reports).

Gastrointestinal
- Very common: dry mouth
- Common: constipation
- Uncommon: nausea/vomiting

Eye
- Common: accommodation abnormal, accommodation disturbances, vision abnormal

General disorders and administration site conditions
- Uncommon: fatigue

Urinary system
- Uncommon: urinary retention

Nervous system
- Uncommon: dizziness, tremor

Vascular
- Uncommon: flushing, decreased blood pressure with drowsiness

Psychiatric
- Very rare: restlessness, confusion

Cardiac
- Very rare: palpitation

Skin and subcutaneous tissue
- Rare: rash due to idiosyncrasy (propiverine hydrochloride) or hypersensitivity (other ingredients, e.g. colorant)

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. Monitoring of intraocular pressure is recommended in patients at risk of developing glaucoma.

Particular attention should be paid to the residual urine volume in cases of urinary tract infections.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING Mictonorm®

Keep out of the reach and sight of children.
Do not store above 30 °C.
Do not use Mictonorm® after the expiry date stated on the label.

6. FURTHER INFORMATION

Obtainable on prescription only.
Mictonorm® does not contain gluten.
This leaflet was last revised on: March 2004

THIS IS A MEDICAMENT
Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly doctors prescription, the method of use and instruction of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicine, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists.