

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Myocholine-Glenwood 25 mg Tablets

Active ingredient

Each tablet contains 25 mg bethanechol chloride

Inactive ingredients and allergens: see section 6, 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

This medicine is intended for stimulating the bladder muscle in cases of postoperative urinary retention in adults.

Therapeutic group: parasympathomimetics, choline esters.

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6);
- you have bronchial asthma;
- you have hypotension (low blood pressure); hypertension (high blood pressure); bradycardia (slow heart rate of under 60 beats per minute); or certain heart diseases (coronary heart disease, atrioventricular conduction disorders);
- you have epilepsy (falling sickness) or Parkinson's disease (paralysis with tremor);
- you have problems regulating the urination reflex due to uncoordinated bladder muscles – when there is no effective relaxation of the sphincter (one of the bladder muscles) at the same time;
- you have recently had urinary or gastrointestinal surgery – due to the risk of inadequate bonding;
- you have a blockage in your bowels or urinary tract;
- you have an overactive thyroid gland;
- you have an overactive vagus nerve; peritonitis;
- you have gastric or intestinal ulcers.

Special warnings about using this medicine

Talk to your doctor or pharmacist before taking Myocholine-Glenwood 25 mg:

- if you have any other medical conditions
- if you have allergies
- if you are taking any other medicine (including over-the-counter products)
- if you have a certain nerve disorder (autonomic neuropathy), for example one that is associated with diabetes.

At the beginning of treatment, sudden changes in posture, such as getting up from sitting, may cause a drop in blood pressure (orthostatic hypotension).

Children and adolescents

This medicine is not intended for children under 18 years old.

Interactions with other medicines

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Particularly if you are taking:

- Anticholinergic drugs (substances which reduce the effect of acetylcholine – a substance produced naturally in the body – such as atropine), quinidine, and procainamide reduce the effect of bethanechol chloride. Similarly, also Myocholine-Glenwood reduces the effect of anticholinergic medicines.
- Cholinesterase inhibitors (substances that inhibit breakdown of acetylcholine, for example in the treatment of Alzheimer's disease or myasthenia gravis) extend the effect of Myocholine-Glenwood 25 mg. Similarly, also Myocholine-Glenwood 25 mg extends the effect of cholinesterase inhibitors.
- Simultaneous intake of ganglion blocking agents may lead to a critical drop in blood pressure, usually with preceding severe abdominal pain.

Using this medicine and food

To prevent nausea, take Myocholine-Glenwood 25 mg with a small amount of liquid, about one hour before or two hours after a meal.

Pregnancy, breastfeeding, and fertility

Taking this medicine during pregnancy and breastfeeding is not recommended. Bethanechol chloride may cause uterine contractions and may pass into breast milk. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Due to possible side effects like feeling dizzy or lightheaded, nausea, low blood pressure, blurred vision and changes in the eyes' accommodation ability, your ability to drive and use machines could be negatively affected.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The usual dosage for adults (unless otherwise prescribed by the doctor) is 1-2 tablets (equivalent to 25-50 mg bethanechol chloride) taken up to 4 times a day (corresponding to a maximum daily dose of 8 tablets or 200 mg of bethanechol chloride).

You will start treatment with a low dose and increase it until you reach the desired effect.

To make it easier to swallow, you may split the tablet immediately before taking it. Swallow both halves of the tablet immediately after you have split it.

You may crush the tablets.

There is no information about chewing the tablets.

Consult your doctor if you feel that the effect of Myocholine-Glenwood is too strong or too weak.

If your condition does not improve within 30 days, contact your doctor. Your doctor will stop your treatment and give you a different one.

If you have accidentally taken a higher dose, contact your doctor as soon as possible.

Symptoms of overdose include nausea, stomach cramps, urgent need to urinate, passing urine and stools involuntarily, sweating, a drop in blood pressure (to the point of shock), impaired heart function, asthma, difficulty breathing with bronchial discharge or heavy salivation.

If you forget to take Myocholine-Glenwood 25 mg

Take the next dose at the scheduled time. Do not take a double dose to make up for a forgotten dose.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Myocholine-Glenwood 25 mg may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Very common side effects (in more than 1 in 10 patients)

- increased salivation and sweating
- increased urge to pass urine
- skin flushing.

Common (in 1 to 10 out of 100 patients)

- heart rate slowed below 60 beats per minute (bradycardia)
- diarrhea
- decreased body temperature (hypothermia)
- drop in blood pressure.

Uncommon side effects (1 to 10 out of 1,000 patients)

- nausea and vomiting
- digestive system disorders
- intestinal colic (spasms)

Rare side effects (1 to 10 out of 10,000 patients)

- Especially at the beginning of treatment, sudden changes in posture may cause dizziness or spinning sensation (orthostatic hypotension).

Very rare side effects (less than 1 in 10,000 patients)

- increased tearing, blurred vision, changes in the eyes' accommodation ability
- chest pain, difficulty breathing, bronchospasm especially in patients who are prone to respiratory complaints
- burping, gastric or intestinal ulcer
- heat rash (miliaria crystallina)
- feeling hot, feeling tense, headache

Side effects whose frequency is not known (frequency cannot be estimated from available data)

- Transient periods of atrial fibrillation (irregular heartbeat) have been observed in patients with a non-functioning thyroid.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor. Do not use the medicine after the expiry date (exp. date) which is stated on the package/blister tray. The expiry date refers to the last day of that month.

Storage conditions

Store below 25°C. Keep in the original package to protect from moisture.

6. Additional information

In addition to the active ingredient, this medicine also contains:

calcium sulfate dihydrate, maize starch, talcum.

What the medicine looks like and contents of the pack: Glenwood-Glenwood 25 mg tablets are flat and white, with a score line and an imprint "MY25" on one side.

Packs contain 50 or 100 tablets.

Not all pack sizes may be marketed.

Registration holder's name and address: Propharm Ltd., POB 4046, 23 Ben-Gurion Street, Zichron Yakov 30900.

Manufacturer's name and address: Glenwood GmbH Pharmazeutische Erzeugnisse, Arabellastrasse 17, 81925 Munich, Germany.

Registration number of the medicine in the Ministry of Health National Drug Registry: 167-20-35286-00

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