

Package leaflet: information for the user

Oxybutynin HCl Auro 2.5 mg, tablets

Oxybutynin HCl Auro 5 mg, tablets

Oxybutynin hydrochloride

Read the entire leaflet carefully before you start using this medicine, because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Please contact your doctor or pharmacist.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Then contact your doctor or pharmacist.

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1. What is Oxybutynin HCl AURO and what is it used for?

Oxybutynin HCl Auro is a medicine that helps relax the smooth muscles of the bladder wall and prevents involuntary contraction (spasm) of these muscles. It helps you control the release of your urine.

This medicine is intended for patients who suffer from symptoms resulting from an overactive bladder muscle. These include involuntary loss of urine or having to urinate very frequently.

When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6;
- if your bladder does not empty completely during urination;
- if you have a narrowing in the gastrointestinal tract, paralysis, or weakness of the intestinal muscles;
- if you have toxic megacolon (a condition associated with an enlarged colon due to poisoning);
- if you have severe ulcerative colitis (severe inflammation of the gastrointestinal tract associated with gastrointestinal ulcers);
- if you have myasthenia gravis (a form of slowly worsening muscle weakness);
- if you have glaucoma (increased pressure and pain in the eyes) or a shallow anterior chamber of the eye;

- if you need to urinate very frequently or often at night, due to a heart disease or kidney disease.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine:

- if the person using the medicine is a child (use under 5 years is not recommended);
- if you have a condition affecting your nervous system (autonomic neuropathy – damage to the nerves that can lead to impaired perception of body temperature, pain, touch, and smell);
- if you have severe abnormalities in your gastrointestinal tract;
- if you have liver or kidney problems;
- if you have a heart condition;
- if you have a rapid heartbeat, overactive thyroid, heart condition including high blood pressure and heart failure, memory loss, or an enlarged prostate. Oxybutynin HCl Auro can worsen the symptoms of these conditions;
- if you suddenly have blurred vision or eye pain. Consult your doctor immediately;
- if you need to use Oxybutynin HCl Auro long-term. Long-term use can contribute to the development of tooth decay, gum inflammation, and fungal infections in the mouth due to reduced saliva production. Consult your dentist for regular dental check-ups;
- if you have indigestion or heartburn caused by a 'hiatus hernia' (diaphragmatic hernia; too large an opening in your diaphragm) or by gastroesophageal reflux (when stomach acid rises and enters the esophagus. This can be painful and feel burning);
- if you are using medicines that can cause inflammation of the esophagus (e.g., bisphosphonates used to treat osteoporosis);
- if you are exposed to high ambient temperatures. Oxybutynin HCl Auro can cause reduced sweating, which may lead to a severe increase in body temperature.

Children and elderly

Children and elderly patients may be more sensitive to the effects of Oxybutynin HCl Auro.

Oxybutynin HCl Auro is not recommended for use in children under 5 years due to insufficient data on safety and efficacy.

Are you using any other medicines?

Are you using any other medicines besides Oxybutynin HCl Auro, have you recently done so, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist.

Consult your doctor if you are using any of the following medicines:

- medicines that have the same side effects as Oxybutynin HCl Auro (especially dry mouth, blurred vision, pupil dilation, reduced sweating, hallucinations, restlessness, loss of perception of time and place, confusion, constipation, dizziness, and drowsiness). The side effects of both medicines may be enhanced;
- amantadine, biperiden, l-dopa (used in the treatment of Parkinson's disease);
- antihistamines (used in the treatment of allergic reactions);
- neuroleptics (phenothiazines such as thioridazine, butyrophenones such as haloperidol, clozapine) (agents to treat certain mental illnesses);
- quinidine (used in the treatment of heart rhythm disorders);

- digitalis (used in the treatment of heart failure);
- tricyclic antidepressants (used in the treatment of depression);
- atropine (e.g., used for the treatment of glaucoma, cardiovascular diseases, or hypertension) and related compounds such as atropine-like antispasmodics (used to treat or prevent muscle spasms);
- dipyridamole (used to treat blood clotting problems);
- cholinesterase inhibitors (used to treat diseases such as Alzheimer's disease). Concurrent use with cholinesterase inhibitors may result in reduced cholinesterase inhibitory efficacy.

Due to a reduction in gastrointestinal function, Oxybutynin HCl Auro may reduce the absorption of other medicines into the blood.

What should you pay attention to with food, drink, and alcohol?

In combination with alcohol, side effects of oxybutynin such as drowsiness, dizziness, and blurred vision may worsen.

**Pregnancy and breastfeeding**

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

**Pregnancy**

During pregnancy, oxybutynin should only be used after consulting your doctor. During the first three months of pregnancy, you should not use this medicine; thereafter, it should only be used during pregnancy if the expected positive effect outweighs the risks of treatment.

**Breastfeeding**

Oxybutynin is excreted in small amounts in breast milk. It is recommended not to breastfeed during treatment with oxybutynin.

**Driving and using machines**

Oxybutynin can cause drowsiness, dizziness, and blurred vision, especially in combination with alcohol. You should take this into account when participating in traffic and operating (dangerous) machines.

**Oxybutynin HCl Auro tablets contain lactose**

If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

**3. How to use this medicine?**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Your doctor has determined a dosage. In general, the following dosages provide sufficient results:

**Adults**

3 times a day 2.5 mg, if necessary, increased to 3-4 times a day 5 mg. Elderly people will be prescribed a lower dosage up to a maximum of 2-3 times a day 5 mg.

#### Children from 5 years

Start with 2.5 mg 2 times a day. The maximum dosage for children aged 5 to 9 years is 7.5 mg divided over 3 times a day. The maximum dosage for children aged 9 to 12 years is 10 mg, divided over 3-4 times a day. For children aged 12 years and older, the standard dosage is 2.5 mg 3 times a day. The maximum dosage is 15 mg, divided over 3-4 times a day.

Never change the dosage yourself and never stop the treatment yourself, even if you have complaints. First consult your doctor. He/she can tell you if you can stop and how best to do so.

#### Method of administration

The tablets are best taken with a generous amount of water (half a glass).

#### Have you used too much of this medicine?

If too much is taken, the mentioned side effects (see under "Possible side effects") may occur more severely. These can lead to changes in blood circulation, reduced breathing, paralysis, and coma.

If you suspect an overdose, you must immediately alert a doctor.

#### Did you forget to use this medicine?

If you forgot to take Oxybutynine HCl Auro, do so as soon as possible. If the time until the next dose is shorter than the time until the missed dose, you do not need to do anything. It is better to skip one dose.

Do not take a double dose of Oxybutynine HCl Auro to make up for the missed dose. Just continue with the prescribed dosing schedule.

#### If you stop using this medicine

If you want to stop taking Oxybutynine HCl Auro, you should first consult with your doctor.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

The following side effects have been reported:

##### Very common: in more than 1 in 10 patients

- constipation, nausea, dry mouth
- dizziness, headache, drowsiness
- dry skin

##### Common: in 1 to 10 in 100 patients

- diarrhea, vomiting
- confusion
- dry eyes
- retention of urine in the bladder (urinary retention)
- flushing of the face

Sometimes: in 1 to 10 out of 1,000 patients

- unpleasant feeling/pain in the abdomen, lack of appetite (anorexia), decreased appetite, difficulty swallowing (dysphagia)

Rare: in 1 to 10 out of 10,000 patients

- a strong heartbeat that may be rapid or irregular, arrhythmias

Not known: cannot be determined from the available data

- urinary tract infections
- gastroesophageal reflux, inability to move food and water through the digestive system due to deterioration of muscle contractions (pseudo-obstruction)
- restlessness, disorientation, irritation, anxiety, hallucinations, nightmares, delusions, memory disorders in the elderly, symptoms of depression, dependence
- memory disorders, seizures
- heat stroke
- increased pressure in the eyeball (acute narrow-angle glaucoma, ocular hypertension), dilated pupil, disturbed vision
- sudden swelling of the tongue, lips, face, and throat (angioedema), rash, hives (urticaria), reduced sweating
- hypersensitivity

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, Website: [www.lareb.nl](http://www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How do you store this medicine?

Keep out of the sight and reach of children.

Store the tablets in the original packaging below 25°C to protect against moisture.

Do not use this medicine after the expiry date. It can be found on the box and the blister strip after Exp. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

## 6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance in this medicine is oxybutynin hydrochloride. Each tablet contains 2.5 mg or 5 mg of oxybutynin hydrochloride.
- The other substances in this medicine are crospovidone, microcrystalline cellulose, lactose monohydrate, and magnesium stearate.

What does Oxybutynin HCl Auro look like and how much is in a package?

Oxybutynin HCl Auro 2.5 mg are white, round tablets with a rounded edge and the inscription 2.5 on one side.

Oxybutynin HCl Auro 5 mg are white, round tablets with a rounded edge and the inscription 5 on one side and a score line on the other side.

The tablets are available in Al/PVC/PVDC blister packaging of 20, 30, 50, 90, or 100 pieces.

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Aurobindo Pharma B.V.

Baarnsche Dijk 1

3741 LN Baarn

Manufacturer

Apotex Nederland BV

Archimedesweg 2

2333 CN Leiden

Netherlands

This medicine is registered under:

RVG 25156 Oxybutynine HCl Auro 2.5 mg, tablets

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This leaflet was last approved in July 2023