

Package leaflet: Information for the user

Oxybutynin Unimedic 0.5 mg/ml intravesical solution. oxybutynin hydrochloride

Read all of this 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.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Oxybutynin Unimedic is and what it is used for

Oxybutynin Unimedic is used to control an overactive bladder that makes you urinate very often or causes incontinence (urine leakage). This can be caused by spina bifida or spinal injury. Oxybutynin Unimedic contains the active substance oxybutynin that works by allowing the bladder to expand and accommodate more urine before feeling the urge to urinate. Thereby the risk of involuntary urine leakage is also reduced.

Oxybutynin Unimedic is given via catheter directly into the bladder, to patients suffering from severe so called anticholinergic adverse events from taking oxybutynin as tablets (see section 4) and that are already using catheter to empty the bladder, so called clean intermittent catheterisation (CIC).

Oxybutynin Unimedic is intended for adults and children over the age of 5 years.

2. What you need to know before you use Oxybutynin Unimedic

Do not use Oxybutynin Unimedic and tell your doctor

- if you are allergic to oxybutynin or any of the other ingredients of this medicine (listed in section 6).
- If you have a rare condition called myasthenia gravis that makes the muscles in the body become weak and tire easily.
- If you have (narrow angle) glaucoma or shallow posterior eye chamber
- If your intestines are obstructed, paralytic or not functioning well
- If you suffer from a severe form of ulcerative colitis (inflammatory bowel disease) ileostomy (surgical opening from the small intestine), colostomy (surgical opening from the large intestine), toxic megacolon (enlarged colon)
- If you experience difficulties in urinating or incomplete bladder emptying during urination
- If you have frequent urination at night caused by heart or kidney disease.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Oxybutynin Unimedic. Elderly persons and children can be more sensitive to the effects of the medicinal product.

This medicinal product should be used with caution in

- diseases of the nervous system (e.g. Parkinsons disease)
- severe gastrointestinal conditions such as diaphragmatic hernia
- liver or kidney disease

Oxybutynin may worsen the symptoms if you have

- overactive thyroid gland (hypertthyroidism)
- certain coronary vascular diseases
- high blood pressure
- enlarged prostate
- irregular or increased heart beat

Since treatment with oxybutynin may cause decreased perspiration, there is an increased risk of heat exhaustion if you are exposed to high environmental temperatures.

Oxybutynin can cause a certain type of glaucoma. Immediately contact your doctor if you experience pain in the eyes or sudden loss of visual acuity.

During long term treatment the risk of lower urinary tract infections is increased. At urinary tract infections during oxybutynin treatment antibiotic treatment should be initiated.

Proper dental care is important since treatment with oxybutynin increases the risk of caries due to dryness of the mouth.

There is a risk that this type of medicines reduce the gastrointestinal movements, affects the attention and causes symptoms such as anxiety, restlessness and sleeping difficulties. The risk is lower when oxybutynin is given via catheter directly into the bladder compared to oral administration.

Children and adolescents

Oxybutynin Unimedic is not recommended for use in children under the age of 5 years.

In children on long term treatment with oxybutynin given via catheter into the urinary bladder, an increased risk of lower urinary tract infections have been observed.

Other medicines and Oxybutynin Unimedic

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Oxybutynin can reduce the gastrointestinal movements and thereby affect the effect of other medicines. Concomitant use with other medicines can also increase the effect of oxybutynin, especially medicines with similar effects or medicines that inhibit the metabolism of oxybutynin. This may increase the risk of dry mouth, constipation, and drowsiness.

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

- phenothiazines, butyrophenones and clozapine (used to treat mental illness)
- amantadine, biperiden and levodopa (used to treat Parkinson's disease)
- tricyclic antidepressants (used to treat depression)
- quinine (used to treat malaria)
- atropine (widens the pupil in the eye, muscle relaxant)
- dipyridamole (reduces the risk of blood clots)
- antihistamines (used to treat allergies)
- itraconazole (used to treat fungal infections)
- erythromycin (used to treat bacterial infections)

- cholinesterase inhibitors (against dementia or certain muscle diseases)

Medicines for angina that should melt under the tongue may dissolve to a lesser extent under the tongue due to mouth dryness. It is therefore recommended to moisten the mouth before taking such a tablet.

Oxybutynin Unimedic with drink and alcohol

Avoid drinking grapefruit juice since this can affect the metabolism of oxybutynin.

Alcohol in combination with this medicine can enhance the drowsiness.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Oxybutynin Unimedic is not recommended during pregnancy.

Oxybutynin Unimedic is not recommended during breast-feeding. Small amounts oxybutynin can be excreted in the breast milk.

Driving and using machines

Oxybutynin Unimedic may cause drowsiness, vertigo or blurred vision. If this happens, driving or using machinery should be avoided.

3. How to use Oxybutynin Unimedic

This medicine is given to you by health care personnel, but if you or relative/caregiver have received adequate training by competent health care personnel, you or your relative/caregiver can administer it at home.

The bladder is emptied from urine via a catheter that is inserted in the urethra, so called clean intermittent catheterisation (CIC). When the bladder is empty the oxybutynin solution and thereafter the saline solution is injected into the bladder via the catheter while it is still in place. Thereafter the catheter is removed. Emptying of the bladder should occur every 4 hours, via CIC.

The dosing is individual and depends on the medical condition and response to the medicine. To ensure the complete dose reaches the bladder your doctor will decide upon a certain amount of the saline solution to be inserted in the catheter after the medicine.

Adults

The dosing is individual and is decided by your doctor. The starting dose is 5 mg (10 ml) in the bladder in the morning and evening. Provided that you can tolerate the side effects, the daily dose may be increased to 5 mg (10 ml) three times a day or 10 mg (20 ml) twice a day to achieve adequate effect.

Use in children and adolescents

Children over the age of 5 years: The dosing is individual and decided by the treating doctor.

The starting dose is 0.1 mg/kg in the bladder in the morning and evening. Provided the child can tolerate the side effects the daily dose may be increased to 0.15 mg/kg twice daily to achieve adequate effect. Not more than 5 mg should be administered per single dose.

Special populations

Elderly or patients with hepatic and renal insufficiency should be treated with caution. A lower dose can be considered.

If you use more Oxybutynin Unimedic than you should

The urinary bladder should be emptied if too much medicine has been used.

To large amount of the medicine can give symptoms such as anxiety, restlessness, confusion, hallucinations, drowsiness, tachycardia, stomach discomfort, cramps, difficulties urinating, fever and dehydration.

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

4. Possible side effects

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

Immediately contact your doctor if you experience pain in the eyes or sudden blurred vision. These can be symptoms of (narrow angle) glaucoma.

If urinary tract infection occurs, a doctor should be contacted and antibiotics given.

The undesirable effects are less pronounced when the medicine is given directly into the bladder compared to oral administration.

Exact frequency of undesirable events, at intravesical administration, is not known.

Dose dependent so called anticholinergic side effects can occur. The following side effects might occur with the frequency not known (cannot be estimated from the available data):

- facial flushing
- headache, dizziness, somnolence, drowsiness
- tachycardia
- dry skin
- mouth dryness, constipation, abdominal discomfort, diarrhoea
- urinary retention
- anxiety, confusion, restlessness, disorientation, agitation
- heat exhaustion due to decreased perspiration
- dry eyes, blurred vision, narrow-angle glaucoma, light hypersensitivity
- urinary tract infections

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Oxybutynin Unimedic

Do not store above 25 °C.

Keep this medicine out of the sight and reach of children.

Opened package should be used immediately.

Do not use this medicine after the expiry date which is stated on the label after EXP.

The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

Declaration of content

1 ml solution contains 0.5 mg of the active substance oxybutynin hydrochloride

The other excipients are sodium chloride, hydrochloric acid (for pH adjustment), water for injections.

What Oxybutynin Unimedic looks like and contents of the pack

Clear colourless solution in a glass vial with a bromobutyl stopper and an aluminum cap.

Packaging size: 10x20 ml.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

Manufacturer:

Apotek Produktion & Laboratorier AB (APL)

Formvagen 5B, Umea Stadsfors.

906 21 Umea

Sweden

This leaflet was last updated 2025-10-31

Detailed information on this medicinal product is available on the website of: {Name of MS/Agency}