

Package leaflet: Information for the user

Velariq 1 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Velariq is and what it is used for
2. What you need to know before you use Velariq
3. How to use Velariq
4. Possible side effects
5. How to store Velariq
6. Contents of the pack and other information

1. What Velariq is and what it is used for

What Velariq is

Velariq is a solution which contains a medicine called oxybutynin hydrochloride. It works by relaxing the muscles of the bladder and stops sudden muscle contractions (spasms). This helps control the release of water (urine).

Velariq solution is to be directly injected into the bladder (intravesical use) through a tube called a catheter.

What Velariq is used for

- Velariq is used in children from 6 years of age and adults for the treatment of an overactive bladder due to a neurological condition, such as:
 - injury of the spinal cord
 - Spina bifida (a birth defect of the spinal cord)
- Velariq is only used if your overactive bladder is not well controlled when you take this kind of medicine orally and if you are currently emptying your bladder by a catheter.

Treatment with Velariq must be started and supervised by a doctor specialised in the treatment of overactive bladder due to neurological disorders.

2. What you need to know before you use Velariq

The following section contains information that is important to know **before** you use this medicine.

Do not use Velariq

- if you are allergic to oxybutynin hydrochloride or any of the other ingredients of this medicine (listed in section 6).

- if you have a rare autoimmune disease called myasthenia gravis that makes the muscles in the body become weak and tire easily.
- if you have a severe stomach or bowel condition such as severe ulcerative colitis or toxic megacolon (an acute widening of the bowel).
- if you suffer from glaucoma (increased pressure in the eyes, sometimes sudden and painful with blurred vision or loss of vision). If you have a family history of glaucoma, tell your doctor.
- if you receive oxygen therapy.

Warnings and precautions

Talk to your doctor before using Velariq if:

- you have an infection of the urinary tract. Your doctor may need to prescribe some antibiotics
- you are above 65 years old as you may be more sensitive to Velariq
- you take sublingual nitrates (a medicine which is placed under the tongue to treat chest pain)
- you have an obstruction of the digestive system, since Velariq might slow down your stomach and bowel movements
- you have a stomach tear (hiatus hernia) or heartburn
- you have a nerve disorder called autonomic neuropathy that affects involuntary body functions including heart rate, blood pressure, perspiration and digestion
- you have problems with memory, language, or thinking abilities
- you have an overactive thyroid gland which can cause increased appetite, weight loss, or sweating
- you have narrowing of the blood vessels that supply blood and oxygen to the heart
- you have heart problems which can cause shortness of breath or ankle swelling
- you have irregular and/or rapid heartbeat
- you have high blood pressure
- you have an enlarged prostate

Velariq may reduce the amount of saliva resulting in tooth decay, gum disease, or fungal infection of the mouth (oral thrush).

Care must be taken when using Velariq in hot weather or if you have a fever. You should for example stay out of the sun and avoid doing sports in the midday heat. This is because Velariq reduces the amount a person sweats. This can lead to heat exhaustion and heat stroke.

Children

This medicine is not recommended for use in children under the age of 6 years because safety and efficacy has not been established in this age group.

Other medicines and Velariq

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Using Velariq at the same time as taking other medicines that have similar side effects such as dry mouth, constipation and sleepiness may increase how often and how severe these side effects are experienced.

The active substance of Velariq is oxybutynin hydrochloride which may slow the digestive tract and thereby influence the adsorption of other oral medicines, or the use of this medicine together with other medicines may increase the effect of oxybutynin hydrochloride.

In particular, tell your doctor if you are taking any of the following medicines:

- Bisphosphonates (used to treat osteoporosis) and other medicines that can cause or worsen an inflammation of the oesophagus
- Ketoconazole, itraconazole or fluconazole (used for the treatment of fungal infections)
- Erythromycin a macrolide antibiotic (used to treat bacterial infections)
- Biperiden, levodopa, or amantadine (used to treat Parkinson's disease)

- Antihistamines (used in the treatment of allergies such as hay fever)
- Phenothiazine, butyrophenones or clozapine (used to treat mental illness)
- Tricyclic antidepressants (used to treat depression)
- Dipyridamole (used to treat blood clotting problems)
- Quinidine (used to treat abnormal heart rhythms)
- Atropine and other anticholinergic medicines (used for treatment in stomach disorders such as irritable bowel syndrome)

Velariq with alcohol

Velariq may cause sleepiness or blurred vision. Sleepiness may be increased by consumption of alcohol.

Pregnancy and breast-feeding

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

Pregnancy

You should not use Velariq if you are pregnant unless your doctor has told you to.

Breast-feeding

Use of Velariq while breast-feeding is not recommended.

Driving and using machines

Velariq may cause sleepiness or blurred vision. Take special care when driving or using machinery.

Velariq contains sodium

This medicine contains 3.5 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0.18% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Velariq

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Dose

Your doctor will calculate the correct amount of Velariq needed to treat your overactive bladder. Do not change your dose on your own.

During the start of your treatment your doctor will regularly check your bladder function and adjust your dose if necessary.

Adolescents (aged 12 years and above), adults and elderly (from 65 years)

The recommended starting dose is normally 10 ml of Velariq per day.

Children (6 - 12 years)

The recommended starting dose is normally 2 ml of Velariq per day.

If you have liver or kidney problems

Please tell your doctor if you have a liver or kidney problem.

Method of administration

Your doctor will only prescribe you Velariq if you or your relatives/carer are familiar with the procedure called “Clean Intermittent Catheterisation (CIC)”. This is a technique which is done at least six times a day to help empty urine from the bladder using a catheter.

CIC stands for Clean Intermittent Catheterisation:

- Clean: as germ-free as possible
- Intermittent: done on a regular schedule many times a day
- Catheterisation: using a catheter, a kind of thin tube, to drain urine out of the bladder

Your doctor will train you and/or your relatives/carer on the procedure of CIC and the administration procedure of Velariq.

The procedure is as follows:

1. Prepare a germ-free environmental condition
2. Insert a sterile disposable catheter into the bladder as shown by your doctor
3. Drain the bladder completely via the catheter
4. Take the syringe from the bag
5. Remove the cap from the syringe
6. Screw a stepped tapered luer-lock adapter on the tip of the syringe
7. Connect the catheter to the syringe with the help of the stepped tapered luer-lock adapter
8. Inject your specific amount of solution into the bladder by constant pressing on the plunger of the syringe
9. If your dose is less than 1 syringe (10 ml), the solution that is not used remains in the syringe which has to be brought to a pharmacy for disposal later
10. Remove the catheter

The injected solution remains in the bladder until the next catheterisation.

Each syringe is for single use only. The urethral catheter, the stepped tapered luer-lock adapter and any unused medicinal product have to be discarded.

If you use more Velariq than you should

If you accidentally applied more than your prescribed dose, empty the bladder immediately via a catheter.

Over dosage can cause symptoms such as restlessness, dizziness, disorders in speech and vision, muscular weakness or faster heartbeat.

If you experience one or more of these symptoms, please contact your doctor or the nearest hospital as soon as possible.

If you forget to use Velariq

If you forget to use a dose at the usual time, use your usual dose in combination with your next catheterisation course. However, if it is nearly time for the next dose, skip the missed dose.

Do not use a double dose to make up for a forgotten dose.

If you are in doubt, always consult your doctor.

If you stop using Velariq

If you stop using Velariq, your symptoms and condition of overactive bladder may return or worsen. Always consult your doctor if you are considering stopping the treatment.

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

4. Possible side effects

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

The side effects occurring most frequently are typical for this kind of medicine and comprise dry mouth, sleepiness and constipation.

The following side effects have been reported for use of oxybutynin hydrochloride, although not all of them have been reported for intravesical use. The frequency of these side effects is not known (frequency cannot be estimated from the available data):

Stop taking Velariq and/or contact a doctor right away if:

- you have a (serious) allergic reaction which causes swelling of the face or throat (angioedema)*
- you feel reduced sweating, leading to overheating in hot environments (heat stroke)*
- you experience sudden eye pain with blurred vision or loss of vision (glaucoma)*

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

Kidneys

- urinary tract infection
- occurrence of bacteria in the urine without causing symptoms
- urgent need to urinate (urinary urgency)
- protein in urine
- blood in urine
- pain when the solution is injected (instilled) into the bladder
- disorder in passing urine or difficulty to start urinating

Mental illnesses

- seeing or hearing things that are not there (hallucinations)
- cognitive disorders
- excessive restlessness and movement (hyperactivity)
- agitation*
- mental clouding or confusion
- difficulty in sleeping
- agoraphobia (e.g. fear of leaving the house, entering shops, being in crowds and in public places)
- inability to concentrate
- anxiety*
- nightmares*
- feeling excessively suspicious and distrustful of others (paranoia)*
- symptoms of depression*
- becoming dependent on oxybutynin (in patients with history of drug or substance abuse)*

Consciousness

- disorientation

- loss of consciousness
- listless
- feeling tired
- sleepiness
- a feeling of dizziness or “spinning”

Eyes

- dry eyes
- abnormal sensation in eye
- inability of the eye to automatically change focus from distance to near objects which can cause blurred vision, double vision, tired eyes
- blurring of vision*
- increased pressure in the eyes*

Heart and blood vessel diseases

- regular but abnormally fast heart rate (supraventricular tachycardia)
- irregular heartbeat (arrhythmia)*
- low blood pressure

Skin

- facial flushing
- rash
- decreased sweating
- nighttime sweating
- itchy, lumpy rash (urticaria)*
- dry skin*
- skin that is more sensitive to the sun (photosensitivity)*

Digestive problems

- constipation
- dry mouth
- abdominal discomfort
- lower or upper abdominal pain
- feeling sick
- indigestion
- diarrhoea
- vomiting*
- loss of appetite (anorexia)*
- decreased appetite*
- difficulty in swallowing (dysphagia)*
- heartburn*
- abnormal bloating/swelling together with pain and feeling or being sick (pseudo-obstruction)*
- change in the sense of taste
- thirst

General disorders

- chest discomfort
- feeling cold
- headache
- disease of the nervous system (anticholinergic syndrome)
- fits (seizures)
- higher level of a hormone called prolactin in the blood. Women might have disruptions in the

normal menstrual period or spontaneous flow of breast milk. Men might experience libido or erection disorders as well as an increase of their breast tissue.

* These side effects have also been reported for this kind of medicines. However, it is not known if these side effects will also occur with Velariq that you have been prescribed.

One patient experienced an oxygen deficiency during home oxygen therapy (see section 2 under “Do not use Velariq”).

Additional side effects in children and adolescents

Children may be more sensitive to the effects of this product, particularly the central nervous system and psychiatric side effects.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Velariq

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

Do not use this medicine after the expiry date which is stated on the label of the syringe and the carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

For single dose use only.

Any unused solution must be discarded immediately.

Do not throw away any medicines via 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

What Velariq contains

- The active substance is oxybutynin hydrochloride

1 ml solution contains 1 mg oxybutynin hydrochloride.

One scaled prefilled syringe with 10 ml sterile solution contains 10 mg oxybutynin hydrochloride.

- The other excipients are: hydrochloric acid, sodium chloride solution (0.9 %).

What Velariq looks like and contents of the pack

Velariq is a clear and colourless solution. It comes as a ready-to-use solution in a 10 ml cycloolefin copolymer prefilled syringe with a synthetic bromobutyl rubber plunger and tip cap. Tray with 12, 96 and 96 (hospital pack) syringes including 12 respectively 96 sterile adapters as application aid.

Not all pack sizes may be marketed.

Marketing Authorisation Holder & Manufacturer

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