Package leaflet: Information for the user.

VESOXX
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 VESOXX 1 mg/ml is and what it is used for

What VESOXX 1 mg/ml is
VESOXX 1 mg/ml 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).
VESOXX 1 mg/ml solution is to be directly injected into the bladder (intravesical use) through a tube called a catheter.

What VESOXX 1 mg/ml is used for
- VESOXX 1 mg/ml 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)
- VESOXX 1 mg/ml 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 VESOXX 1 mg/ml 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 VESOXX 1 mg/ml

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

Do not use VESOXX 1 mg/ml
- 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 experience difficulties in urinating or incomplete bladder emptying during urination
- if you have frequent urination at night caused by heart or kidney disease
- if you receive oxygen therapy.

Warnings and precautions
Talk to your doctor before using VESOXX 1 mg/ml 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 VESOXX 1 mg/ml
- 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 VESOXX 1 mg/ml 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 heart beat
- you have high blood pressure
- you have an enlarged prostate

VESOXX 1 mg/ml may reduce the amount of saliva resulting in tooth decay, gum disease, or fungal infection of the mouth (oral thrush).

Oxybutynin can cause a certain type of glaucoma. Immediately contact your doctor if you experience blurred vision, loss of vision or have any pain in the eye. You should have your visual acuity and intraocular pressure checked occasionally during treatment.

Care must be taken when using VESOXX 1 mg/ml 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 VESOXX 1 mg/ml reduces the amount a person sweats. This can lead to heat exhaustion and heat stroke.

Children and adolescents
VESOXX 1 mg/ml is not recommended for use in children under the age of 6 years.

Other medicines and VESOXX 1 mg/ml
Tell your doctor if you are taking, have recently taken or might take any other medicines.

Using VESOXX 1 mg/ml 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 VESOXX 1 mg/ml 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)
- cholinesterase inhibitors (against dementia or certain muscle diseases)

Medicines for angina (tightness in the chest due to reduced blood flow to the heart) 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 VESOXX 1 mg/ml.

VESOXX 1 mg/ml with alcohol
VESOXX 1 mg/ml 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 VESOXX 1 mg/ml if you are pregnant unless your doctor has told you to.

Breast-feeding
Use of VESOXX 1 mg/ml while breast-feeding is not recommended.

Driving and using machines
VESOXX 1 mg/ml may cause sleepiness or blurred vision. Take special care when driving or using machinery.

VESOXX 1 mg/ml contains sodium
This medicine contains 3.56 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 VESOXX 1 mg/ml

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 VESOXX 1 mg/ml 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 (over 65 years)
The recommended starting dose is normally 10 ml of VESOXX 1 mg/ml per day.

Children (6 - 12 years)
The recommended starting dose is normally 2 ml of VESOXX 1 mg/ml 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 VESOXX 1 mg/ml 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 VESOXX 1 mg/ml.

The procedure is as follows:
1. Disinfect your hands as indicated on the packaging of the disinfectant. Open the packaging of the pre-filled syringe at the spot marked for this purpose.
2. Remove the pre-filled syringe from the packaging. Remove the cap by turning it slightly.
3. TIP: If you were prescribed less than the amount in the syringe, inject out the unneeded amount before instillation unless user responsibility is taken for using the remaining amount in the syringe (see section 5) (Unused medicinal product or waste material is to be disposed of in accordance with national requirements. For the sake of the environment, do not dispose of the medicines in waste water).
4. Now put the syringe back into its packaging without touching the tip of syringe.
5. Disinfect your hands and begin catheterisation. (Instructions can be found at: www.farco.de/isk).
6. Empty your bladder completely through the catheter and make sure that the catheter is still in the bladder before you start instillation.
7. Take the pre-filled syringe out of the packaging again and connect it to the catheter.
8. Instill the contents of the pre-filled syringe into the bladder by pressing the plunger of the syringe. Remove the pre-filled syringe together with the catheter for disposal.
9. Unused medicinal product or waste material is to be disposed of in accordance with national requirements. For the sake of the environment, do not dispose of the medicines in waste water.

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

Each syringe is for single use only. The urethral catheter and any unused medicinal product have to be discarded.

If you use more VESOXX 1 mg/ml than you should
If you accidentally applied more than your prescribed dose, empty the bladder immediately via a catheter.

Overdosage 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 VESOXX 1 mg/ml
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 VESOXX 1 mg/ml
If you stop using VESOXX 1 mg/ml, 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 VESOXX 1 mg/ml 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
- listlessness
- 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 heart beat (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 cycle or spontaneous flow of breast milk. Men might experience libido or erectile 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 VESOXX 1 mg/ml that you have been prescribed.

One patient experienced an oxygen deficiency during home oxygen therapy (see section 2 under "Do not use VESOXX 1 mg/ml").

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 to the Federal Institute for Drugs and Medical Devices, Pharmacovigilance Department, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store VESOXX 1 mg/ml

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 temperature storage conditions.

For single dose use only.
If not used immediately the storage time and storage conditions before administration are the responsibility of the user.

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 VESOXX 1 mg/ml 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, water for injections

What VESOXX 1 mg/ml looks like and contents of the pack
VESOXX 1 mg/ml is a clear and colourless solution.

It comes as a ready-to-use solution in a 10 ml polypropylene prefilled syringe with a synthetic bromobutyl rubber plunger and tip cap.

Carton with 100 prefilled syringes. Carton with 12 syringes for direct connection with standard catheter systems.

Not all pack sizes listed may be marketed.

Marketing Authorisation Holder
FARCO-PHARMA GmbH
Gereonsmühlengasse 1-11
50670 Cologne
Germany

Manufacturer
Almed GmbH
Motzener Strasse 41
12277 Berlin
Germany

This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Belgium:	VESOXX 1 mg/ml
Germany	VESOXX 1 mg/ml Lösung zur intravesikalen Anwendung
Italy:	Vesoxx 1 mg/ml, soluzione endovesicale
Luxembourg:	VESOXX
Netherlands:	VESOLOX 1 mg/ml oplossing voor intravesicaal gebruik
Austria:	VESOXX 1 mg/ml solution for intravesical use
Poland:	Vesoxx
Portugal:	Vesoxx 1 mg/ml solução intravesical
Sweden:	Vesoxx 1 mg/ml intravesical lösning
Slovakia:	VESOXX 1 mg/ml
Spain	Vesoxx 1 mg/ml solución intravesical
Czech Republic:	VESOXX
United Kingdom (Northern Ireland):	Vesoxx 1 mg/ml intravesical solution

This leaflet was last revised in January 2024.

The following information is intended for healthcare professionals only:

Posology
Initial dose adjustment shall be done by a neuro-urologist under close urodynamic control.

There are no fixed rules for the dose regimen as high interindividual differences in bladder pressure and doses required to improve neurogenic detrusor overactivity exist. The dose regimen (doses and timings) must therefore be determined individually according to the patient´s need.

Individual dosages will be applied to control uro-dynamic parameters sufficiently (maximum detrusor pressure < 40 cm H_2O) aiming at complete inhibition of neurogenic detrusor overactivity.

In the course of intravesical oxybutynin therapy, urodynamic parameters shall be controlled in regular intervals as defined by the attending urologist.

Paediatric population
The safety and efficacy of oxybutynin hydrochloride in children aged 0 to 5 years of age have not yet been established.

Dose recommendations in the following age groups
The dose recommendations have been calculated according to the body weight percentiles of the different age groups (table 1).

Table 1: Dose recommendations in the following age groups

Age group	Age [years]	Recommended daily starting dose [mg]	Recommended total daily dose [mg]
Children	6 - 12	Individual, see below	2 - 30
Adolescents	12 - 18	10	10 - 40
Adults	19 - 65	10	10 - 40
Elderly	over 65	10	10 - 30

If higher doses than the starting dose are considered necessary, the dose should be increased using a step-wise approach until neurogenic detrusor overactivity is sufficiently controlled to allow close monitoring of both efficacy and safety. The required daily maintenance doses may be divided into several applications (table 2 and 3). Given a number of six clean intermittent catheterisations (CICs) per day, the following dose scheme is recommended:

Table 2: Recommended dose scheme (children from 6 - 12 years)

Daily dose [mg]	Administered dose per application [mg]					
	CIC 1	CIC 2	CIC 3	CIC 4	CIC 5	CIC 6
2	2	-	-	-	-	-
5	5	-	-	-	-	-
10	5	-	5	-	-	-
15	5	-	5	-	5	-
20	10	-	10	-	-	-
30	10	-	10	-	10	-

Table 3: Recommended dose scheme for 10 mg starting doses (adolescents from 12 years and above, adults and elderly)

Daily dose [mg]	Administered dose per application [mg]					
	CIC 1	CIC 2	CIC 3	CIC 4	CIC 5	CIC 6
10	5	-	5	-	-	-
20	10	-	10	-	-	-
30	10	-	10	-	10	-
40	10	10	10	-	10	-

Children (from 6 years – 12 years)
The dosing is individual with a starting dose of 0.1 mg/kg intravesically in the morning. The dose can be adjusted after one week of treatment. Lowest effective dosing should be chosen. The daily dose may be increased up to 30 mg daily to achieve adequate effect, provided that side effects are tolerated. Not more than 10 mg should be administered per single dose.
The safety and efficacy of oxybutynin hydrochloride in children below 6 years of age have not yet been established.

Elderly (over 65 years)
As with other anticholinergic drugs caution should be observed in frail and elderly patients, especially if doses higher than 30 mg per day are considered as required.

Hepatic or renal impairment
VESOXX 1 mg/ml should be used with caution in patients with hepatic or renal impairment. The use of VESOXX 1 mg/ml in those patients should be carefully monitored and dose reductions may be needed.