

Prescribing information: Velariq® (oxybutynin hydrochloride) 1 mg/ml, intravesical solution

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MEDICE UK on 020 4582 2845, pv-uk@medice.co.uk

Information about this product, including adverse reactions, precautions, contraindications, and method of use can be found at <https://www.medicines.org.uk/emc>.

Indication: Velariq is indicated for the suppression of neurogenic detrusor overactivity (NDO) in children from 6 years of age and adults, who are managing bladder emptying by clean intermittent catheterisation, not adequately managed with oral anticholinergics.

Dosage and administration: 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 H₂O) aiming at complete inhibition of neurogenic detrusor overactivity

Dose adjustments: The dose recommendations have been calculated according to the body weight percentiles of the different age groups.

Age Group	Age [years]	Recommended daily starting dose [mg]	Recommended total daily dose [mg]
Children	6-12	2	2-30
Adolescents	12-18	10	10-40
Adults	19-65	10	10-40
Elderly	From 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. Refer to SPC for full information and recommended dose schemes.

Administration: Intravesical use. To ensure safe and effective treatment, patients must be familiar with the procedure of clean intermittent catheterisation (CIC). The patients and/or relative, carer shall be trained on CIC and the administration procedure by specialised health care professionals. Refer to SPC for full administration instructions. The duration of treatment depends on the symptoms, the underlying disease and / or the treatment goal and is determined by the treating physician.

Contraindications: Hypersensitivity to the active substance or to any of the excipients. Severe gastro-intestinal conditions (e.g. severe ulcerative colitis and toxic megacolon). Myasthenia gravis. Narrow angle glaucoma and in patients who are at risk for these conditions. Concomitant oxygen therapy.

Special warnings and precautions: If urinary tract infection is present, an appropriate antibacterial therapy should be started. Velariq should be used with caution in elderly patients, who may be more sensitive to the effects of centrally acting anticholinergics. Psychiatric and central nervous system (CNS) anticholinergic events like sleep disorders (e.g. insomnia) and cognitive disorders have been associated with oxybutynin use, especially in elderly patients. Caution should be exercised when oxybutynin is administered concomitantly with other anticholinergic medicines.

If a patient experiences such events, drug discontinuation should be considered. The use/administration of oxybutynin products may warrant the following cautionary statements: anticholinergic medicinal products may decrease gastrointestinal motility and should be used with caution in patients with gastrointestinal obstructive disorders because of the risk of gastric retention. They should also be used with caution in patients who have hiatus hernia/gastro-oesophageal reflux. Anticholinergic medicinal products should be used with caution in patients who have autonomic neuropathy or cognitive impairment. Patients should be informed that heat prostration can occur when anticholinergics such as oxybutynin are used in a hot environment. Oxybutynin may exacerbate the symptoms of hyperthyroidism, coronary heart disease, congestive heart failure, cardiac arrhythmias, tachycardia, hypertension and prostatic hypertrophy. Oxybutynin may lead to suppressed salivary secretions which could result in dental caries, parodontosis or oral candidiasis. **Paediatric population:** In children Velariq should be used with caution as they may be more sensitive to the effects of the product, particularly the CNS and psychiatric adverse reactions. This medicinal product contains 3.5 mg sodium per ml, equivalent to 0.18% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Interactions: Anticholinergic agents may potentially alter the absorption of some concomitantly administered medicinal products due to anticholinergic effects on gastrointestinal motility. Anticholinergic medicinal products should be used with caution in patients who are concurrently taking medicinal products (such as bisphosphonates) that can cause or exacerbate oesophagitis. Interactions with medicinal products that inhibit cytochrome P 450 isoenzyme CYP 3A4 cannot be ruled out. This should be borne in mind when using azole antifungals (e.g. ketoconazole) or macrolide antibiotics (e.g. erythromycin) concurrently with oxybutynin. The anticholinergic activity of oxybutynin is increased by concurrent use of other anticholinergics or medicinal products with anticholinergic activity, such as amantadine and other anticholinergic antiparkinsonian medicinal products (e.g. biperiden, levodopa), antihistamines, antipsychotics (e.g. phenothiazines, butyrophenones, clozapine), quinidine, tricyclic antidepressants, atropine and related compounds like atropinic antispasmodics, dipyridamole. Oxybutynin may antagonise prokinetic therapy.

Fertility, pregnancy and lactation: Velariq should not be used during pregnancy unless the clinical condition of the woman requires treatment. Use of oxybutynin is not recommended during breast-feeding. Data on possible effects of the use of oxybutynin on human male and female fertility are not available.

Undesirable effects: Because Velariq may produce somnolence, or accommodation disorders, patients should be advised to exercise caution when driving or using machinery. Patients should be informed that alcohol may enhance the drowsiness caused by anticholinergic agents such as oxybutynin. Undesirable effects observed with oxybutynin hydrochloride such as dry mouth, somnolence, and constipation mainly reflect the typical anticholinergic properties of the active ingredient. Adverse reactions from clinical trials with intravesical use of oxybutynin hydrochloride are unknown in frequency. Prescribers should consult the SPC in relation to full side effect information. Children may be more sensitive to the effects of the product, particularly the CNS and psychiatric adverse reactions. Adverse reactions known to be associated with anticholinergic therapy, but not observed with intravesical use of oxybutynin during clinical studies are vomiting, anorexia, decreased appetite, dysphagia, gastroesophageal reflux disease, pseudo-obstruction in patients at risk, confusional state, agitation, anxiety, nightmares, paranoia, symptoms of depression, dependence to oxybutynin, arrhythmia, heat stroke, angle closure glaucoma, ocular hypertension, dry skin, angioedema, urticaria, photosensitivity, hypersensitivity

Legal classification: POM.

Marketing Authorisation Number, pack size and price: PL 11243/0046. 12 pre-filled syringes £204.00, 96 pre-filled syringes £1,632.00

Marketing Authorisation Holder: MEDICE Arzneimittel Pütter GmbH & Co. KG, Kuhloweg 37, 58638 Iserlohn, Germany.

Marketed in the UK by MEDICE UK Ltd. Ground Floor, Unit B, The Chase, Foxholes Business Park, Hertford, Herts, SG13 7NN. Tel: 020 4582 2845. Email: medicalinformation@medice.co.uk

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