

Summary Public Assessment Report

Oxybutynin Unimedic (oxybutynin hydrochloride)

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oxybutynin hydrochloride

Intravesical solution, 0,5 mg/ml

This is a summary of the public assessment report (PAR) for Oxybutynin Unimedic. It explains how Oxybutynin Unimedic was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Oxybutynin Unimedic.

For practical information about using Oxybutynin Unimedic, patients should read the package leaflet or contact their doctor or pharmacist.

What is Oxybutynin Unimedic and what is it used for?

Oxybutynin Unimedic is a medicine with ‘well-established use’. This means that the medicinal use of the active substance of Oxybutynin Unimedic is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Oxybutynin Unimedic is used to control an overactive bladder that makes patients urinate very often or causes incontinence (urine leakage). This can be caused by spina bifida or spinal injury.

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 of the package leaflet) 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.

How does Oxybutynin Unimedic work?

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.

How is Oxybutynin Unimedic used?

The pharmaceutical form of Oxybutynin Unimedic is intravesical solution for intravesical use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Oxybutynin Unimedic have been shown in studies?

As *oxybutynin hydrochloride* is a well-known substance, and its use in the treatment of *an overactive bladder* is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of *oxybutynin hydrochloride* in the treatment of *an overactive bladder*.

What are the possible side effects of Oxybutynin Unimedic?

For the full list of all side effects reported with Oxybutynin Unimedic, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Oxybutynin Unimedic approved?

The use of Oxybutynin Unimedic in the treatment of an overactive bladder is well-established in medical practice and documented in the scientific literature. No new or unexpected safety concerns arose from these applications. Therefore, the Medical Products Agency in Sweden decided that Oxybutynin Unimedic's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Oxybutynin Unimedic?

A risk management plan has been developed to ensure that Oxybutynin Unimedic is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Oxybutynin Unimedic, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Oxybutynin Unimedic

The full PAR for Oxybutynin Unimedic can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Oxybutynin Unimedic, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2021-02.