

- During an eye operation for clouding of the lens (cataracts) or for increased pressure in the eye (glaucoma), the pupil (the black circle in the center of the eye) may not enlarge properly. Also, the iris (the colored part of the eye) can become flaccid during surgery.
- Voice disorder.
- Liver disorder.
- Muscular weakness.
- Kidney disorder.
- Altered vision.
- Nosebleeds (epistaxis).

How to store URALOS MAX
 - Store between 15 and 30 °C
 - Keep out of the reach of children.

Presentation
 Packages with 30 prolonged-release tablets.

If you take higher doses of URALOS MAX than you should.
 In the event of an overdose, go to the nearest Hospital or contact the Poison Control Centers:
 Hospital A. Posadas: (011) 4654-6648 / 4658-7777.
 Ricardo Gutiérrez Pediatric Hospital: (011) 4962-6666 / 2247.
 Optionally other Poison Centers.

"This medicine has been prescribed only for your current medical problem. Do not recommend it to other people".
"In the event of any problem with the product, the patient can fill out the form that is on the ANMAT Web Page <http://anmat.gov.ar/farmacovigilancia/Notificar.asp> or call ANMAT responde 0800-333-1234"

Technical Direction: Dr. Luis M. Radici - Pharmacist.
 REGISTRATION AUTHORIZED BY THE MINISTRY OF HEALTH.
 Certificate N° 58.134
 Manufacturing by Laboratorios CASASCO S.A.I.C.
 Av. Boyacá 237 - Autonomous City of Buenos Aires

URALOS® MAX



TAMSULOSIN
 SOLIFENACIN

PROLONGED-RELEASE TABLETS

INFORMATION FOR THE PATIENT CONSULT YOUR DOCTOR

Read this patient information both before you start taking URALOS MAX and each time you refill the prescription as there may be new information. This information does not replace your doctor's advice regarding your illness or your treatment.

What is URALOS MAX and what is it used for?
 URALOS MAX is a combination of two different medicines, Tamsulosin and Solifenacin, in one tablet. Tamsulosin belongs to a group of medicines called alpha-blockers and Solifenacin belongs to a group of medicines called anticholinergics. URALOS MAX is used in men to treat both so-called symptoms (moderate to severe filling) and so-called lower urinary tract emptying symptoms caused by problems related to the bladder and by an enlarged prostate (benign prostatic hyperplasia). URALOS MAX is used when previous monotherapy treatment for this condition failed to adequately relieve symptoms. When the size of the prostate increases, urinary problems (emptying symptoms) such as delayed urination (difficulty starting urination), reduced urine flow (weak stream), dribbling, and the feeling of incomplete emptying of the bladder may appear. At the same time, the bladder is also affected and contracts spontaneously at times when urination is not desired. This causes filling symptoms such as changes in bladder sensation, urgency (having a sudden strong urge to urinate without warning) and having to urinate more often. Tamsulosin allows urine to pass more easily through the urethra and makes urination easier. Solifenacin reduces involuntary bladder contractions and increases the amount of urine your bladder can store. Therefore, you can wait longer before you have to go to the bathroom.

Before using URALOS MAX
Do not use URALOS MAX if:
 - you are allergic to Tamsulosin or Solifenacin or any of the other ingredients in this medicine.
 - you are undergoing kidney dialysis.
 - you have severe liver disease
 - you suffer from severe kidney disease and if, at the same time, you are being treated with medicines that can decrease the elimination of URALOS MAX from the body (for example Ketoconazole, Ritonavir, Nelfinavir, Itraconazole). Your doctor or pharmacist will inform you if this is the case.
 - you suffer from moderate liver disease AND if, at the same time, you are being treated with medicines that can decrease the elimination of URALOS MAX from the body (for example, Ketoconazole, Ritonavir, Nelfinavir, Itraconazole). Your doctor or pharmacist will inform you if this is the case.
 - have a severe stomach or intestinal condition (including toxic megacolon, a complication associated with ulcerative colitis).
 - you have a muscle disease called myasthenia gravis, which can cause extreme weakness of certain muscles.
 - suffer from increased pressure in the eyes (glaucoma), with gradual loss of sight.
 - you suffer from fainting due to a drop in blood pressure when changing posture (sitting or standing up); this is called orthostatic hypotension.
 Tell your doctor if you think you have any of these conditions.

Take special care with URALOS MAX
 Talk to your doctor or pharmacist before using URALOS MAX if:
 - you have difficulty eliminating fluid (urinary retention).
 - you have any obstruction of the digestive system.
 - you are at risk of decreased activity of the digestive system (stomach and bowel movements). Your doctor will inform you if this is the case.
 - you have a diaphragm tear (hiatal hernia) or heartburn and/or if, at the same time, you are taking medicines that can cause or worsen esophagitis.
 - you suffer from a certain type of nerve disease (autonomic neuropathy).
 - you suffer from severe kidney disease.



- you suffer from moderate liver disease.
 Regular check-ups are necessary to monitor the development of the condition for which you are being treated.
 URALOS MAX can affect your blood pressure which may make you feel dizzy, lightheaded or, rarely, faint (orthostatic hypotension). If you experience any of these symptoms you will need to sit or lie down until they are gone.
 If you are going to undergo or are scheduled for eye surgery due to clouding of the lens (cataracts) or increased pressure in the eyes (glaucoma), please inform your ophthalmologist that you have previously used, are using, or have planned to use URALOS MAX. The specialist can then take appropriate precautions with regard to the medication and surgical techniques to be used.
 Ask your doctor whether or not you should postpone or temporarily stop taking this medicine when you are having eye surgery for clouding of the lens (cataract) or increased pressure in the eye (glaucoma).

Taking other medicines at the same time
 Please inform your doctor or pharmacist if you are using, have recently used or might take any other medicine.
 It is especially important that you tell your doctor if you are using:
 - medicines such as Ketoconazole, Erythromycin, Ritonavir, Nelfinavir, Itraconazole, Verapamil, Diltiazem and Paroxetine which reduce the rate at which URALOS MAX is eliminated from the body.
 - other anticholinergic medicines since the effects and side effects of both medicines can be intensified if you are taking two medicines of the same type.
 - cholinergics, since they can reduce the effect of URALOS MAX.
 - medicines such as Metoclopramide and Cisapride, which can speed up the functioning of the digestive system. URALOS MAX can reduce its effect.
 - other alpha-blockers, as they can cause an unwanted drop in blood pressure.
 - medicines such as bisphosphonates, which can cause or exacerbate inflammation of the esophagus (esophagitis).

Pregnancy, lactation, and fertility
 URALOS MAX is not indicated for use in women.
 In men, abnormal ejaculation (impaired ejaculation) has been reported.
 This means that semen is not released through the urethra, but instead goes to the bladder (retrograde ejaculation) or that the ejaculated volume is reduced or absent (ejaculatory insufficiency). This phenomenon is harmless.

How to use URALOS MAX
 Follow exactly the instructions of administration of this medicine indicated by your doctor or pharmacist. If in doubt, ask your doctor or pharmacist again.
 The maximum daily dose is one tablet containing 0.4mg of Tamsulosin and 6mg of Solifenacin, taken orally.
 It can be taken with or without food, depending on your preferences. Do not crush or chew the tablet.

Use in children and adolescents
 Do not give this medicine to children and adolescents.

Effects on the ability to drive vehicles
 URALOS MAX can cause dizziness, blurred vision, tiredness and, less frequently, drowsiness. If you experience these side effects, do not drive, or operate machinery.
 Joint use of URALOS MAX with food and drink
 URALOS MAX can be taken with or without food, according to your preferences.

Proper use of URALOS MAX medicine
If you forget to take URALOS MAX
 Take your next URALOS MAX tablet normally. Do not take a double dose to make up for a forgotten dose.

If you stop taking URALOS MAX
 If you stop taking URALOS MAX, your initial complaints may come back or get worse. Always consult your doctor if you are considering stopping treatment.
 If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

To bear in mind while taking URALOS MAX
Undesirable effects (side effects)
 Like all medicines, URALOS MAX can cause side effects, although not everyone gets them.
 The most serious side effect that has been observed infrequently (affecting up to 1 in 100 men) during

treatment with combined Tamsulosin/Solifenacin in clinical studies is acute urinary retention, which is a sudden inability to pee. If you think you may have it, see your doctor immediately. You may need to stop taking URALOS MAX.
 URALOS MAX may cause allergic reactions:
 - Uncommon signs of allergic reactions may include a skin rash (which may be itchy) or hives (urticaria).
 - Rare symptoms include swelling of the face, lips, mouth, tongue, or throat which may cause difficulty in swallowing or breathing (angioedema).
 Angioedema has been reported rarely with Tamsulosin and rarely with Solifenacin. In the event of angioedema, URALOS MAX treatment should be discontinued immediately and permanently.
 If you experience an allergic crisis or a severe skin reaction (for example blistering and peeling of the skin), you should inform your doctor immediately and stop using URALOS MAX. Appropriate treatment and/or measures should be applied.

Common side effects (may affect up to 1 in 10 men)
 - dry mouth
 - constipation
 - indigestion (dyspepsia)
 - dizziness
 - blurred vision
 - fatigue
 - abnormal ejaculation (ejaculation disorder). This means that semen is not released through the urethra, but instead goes to the bladder (retrograde ejaculation) or that the ejaculated volume is reduced or absent (ejaculatory insufficiency). This phenomenon is harmless.
 - Feeling dizzy (nausea)
 - Abdominal pain

Uncommon side effects (may affect up to 1 in 100 men)
 - Somnolence
 - Itching (pruritus)
 - Urinary tract infection, bladder infection (cystitis)
 - Disorder of sense of taste (dysgeusia)
 - Dry eyes
 - Nasal dryness
 - Reflux disease (gastroesophageal reflux)
 - Dry throat
 - Dry skin
 - Difficulty urinating
 - Fluid accumulation in the legs (edema)
 - Headache
 - Rapid or irregular heartbeat (palpitations)
 - Feeling dizzy or weak especially when standing up (hypotension orthostatic)
 - Runny or blocked nose (rhinitis)
 - Diarrhea
 - Vomiting
 - Tiredness (asthenia)

Rare side effects (may affect up to 1 in 1,000 men)
 - Accumulation of large amount of hardened stool in the large intestine (fecal impaction)
 - feeling faint (syncope)
 - skin allergy causing swelling of the tissue under the surface of the skin (angioedema).
 Very rare side effects (may affect up to 1 in 10,000 men)
 - Hallucinations, confusion
 - Allergic skin reaction (erythema multiforme)
 - Long-lasting and painful erection (usually not during sexual activity) (priapism).
 - Rash, inflammation and blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages, or genitalia (Stevens Johnson syndrome)

Not known frequency (frequency cannot be estimated from the available data)
 - Decreased appetite.
 - High levels of potassium in the blood (hyperkalaemia) that can cause abnormal heart rhythm.
 - Increased pressure in the eyes (glaucoma).
 - Irregular or abnormal heartbeat (QT interval prolongation, Torsades de Pointes, atrial fibrillation, arrhythmia).
 - Fast heartbeat (tachycardia).
 - Shortness of breath (dyspnea).