

Package leaflet: Information for the user

Vesomni® 6 mg/0.4 mg modified release tablets

solifenacin succinate/tamsulosin 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 Vesomni is and what it is used for
2. What you need to know before you use Vesomni
3. How to use Vesomni
4. Possible side effects
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1. What Vesomni is and what it is used for

Vesomni is a combination of two different medicines called solifenacin and tamsulosin in one tablet. Solifenacin belongs to a group of medicines called anticholinergics and tamsulosin belongs to a group of medicines called alpha-blockers. Vesomni is used in men to treat both moderate to severe storage symptoms and voiding symptoms of the lower urinary tract which are caused by bladder problems and an enlarged prostate (benign prostatic hyperplasia). Vesomni is used when previous treatment with a monoprotocol for this condition did not relieve symptoms adequately.

As the prostate grows, it can lead to urinary problems (voiding symptoms) such as hesitancy (difficulty to start urinating), difficulty urinating (poor stream), dribbling and feeling of incomplete bladder emptying. At the same time, the bladder is also affected and contracts spontaneously at times you do not want to void. This causes storage symptoms such as changes in bladder sensation, urgency (having a strong, sudden desire to urinate without prior warning), and having to urinate more frequently.

Solifenacin reduces the undesired contractions of your bladder and increases the amount of urine that your bladder can hold. Therefore you can wait longer before you have to go to the toilet. Tamsulosin enables urine to pass more readily through the urethra and facilitates urination.

2. What you need to know before you use Vesomni

Do not use Vesomni if:

- you are allergic to solifenacin or tamsulosin or any of the other ingredients of this medicine (listed in section 6).
- you are undergoing kidney dialysis.
- you have a severe liver disease.
- you suffer from severe kidney disease AND if, at the same time, you are being treated with medicines that may decrease the removal of Vesomni from the body (for example ketoconazole, ritonavir, nelfinavir, itraconazole). Your doctor or pharmacist will have informed 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 may decrease the removal of Vesomni from the body (for example ketoconazole, ritonavir, nelfinavir, itraconazole). Your doctor or pharmacist will have informed you if this is the case.
- you have a severe stomach or bowel condition (including toxic megacolon, a complication associated with ulcerative colitis).
- you suffer from a muscle disease called myasthenia gravis, which can cause an extreme weakness of certain muscles.
- you suffer from increased pressure in the eyes (glaucoma), with gradual loss of eye sight.
- you suffer from fainting due to reduced blood pressure when changing posture (going to sit up or stand up); this is called orthostatic hypotension.

Tell your doctor if you think that any of these conditions apply to you.

Warnings and precautions

Talk to your doctor or pharmacist before using Vesomni if:

- you have an inability to pass water (urinary retention).
- you have some obstruction of the digestive system.
- you are at risk of your digestive system slowing down (stomach and bowel movements). Your doctor will have informed you if this is the case.

- you have a stomach tear (hiatus hernia) or heartburn and/or if, at the same time, you are taking medicines that can cause or worsen oesophagitis.
- you suffer from a certain type of nervous disease (autonomic neuropathy).
- you suffer from severe kidney disease.
- you suffer from moderate liver disease.

Periodic medical examinations are necessary to monitor the development of the condition you are being treated for. Vesomni can affect your blood pressure which can make you feel dizzy, light headed or rarely can make you faint (orthostatic hypotension). You should sit or lie down if you experience any of these symptoms until they disappear. If you are undergoing or have been scheduled for eye surgery because of cloudiness of the lens (cataract) or increased pressure in the eyes (glaucoma), please inform your eye specialist that you have previously used, are using or are planning to use Vesomni. The specialist can then take appropriate precautions with respect to medication and surgical techniques to be used. Ask your doctor whether or not you should postpone or temporarily stop taking this medicine when undergoing eye surgery because of a cloudy lens (cataract) or increased pressure in the eye (glaucoma).

Children and adolescents

Do not give this medicine to children and adolescents.

Other medicines and Vesomni

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

It is especially important to inform your doctor if you are using:

- medicines like ketoconazole, erythromycin, ritonavir, nelfinavir, itraconazole, verapamil, diltiazem, and paroxetine which decrease the rate at which Vesomni is removed from the body.
- other anticholinergic medicines, as effects and side effects of both medications can be enhanced if you are taking two medicines of the same type.
- cholinergics, as they can reduce the effect of Vesomni.
- medicines like metoclopramide and cisapride, which make the digestive system work faster.
- Vesomni can reduce their effect.
- other alpha-blockers, as this may cause an unwanted decrease in blood pressure.
- medicines such as bisphosphonates, that can cause or exacerbate inflammation of the gullet (oesophagitis).

Vesomni with food and drink

Vesomni can be taken with or without food, according to your preference.

Pregnancy, breast-feeding and fertility

Vesomni is not indicated for use by women.

In men, abnormal ejaculation has been reported (ejaculation disorder). This means that the semen does not leave the body via the urethra, but instead goes into the bladder (retrograde ejaculation) or the ejaculation volume is reduced or absent (ejaculation failure). This phenomenon is harmless.

Driving and using machines

Vesomni might cause dizziness, blurred vision, tiredness and, uncommonly, sleepiness. If you suffer from these side effects, do not drive or operate machinery.

3. How to use Vesomni

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The maximum daily dose is one tablet containing 6 mg of solifenacin and 0.4 mg of tamsulosin, taken by mouth. It can be taken with or without food, according to your preference. Do not crush or chew the tablet.

If you take more Vesomni than you should

If you have taken more tablets than you have been told to take, or if someone else accidentally takes your tablets, contact your doctor, pharmacist or hospital immediately for advice. In case of an overdose your doctor may treat you with activated charcoal; emergency stomach washout may be useful if performed within 1 hour of overdose. Do not induce vomiting.

Symptoms of overdose may include: dry mouth, dizziness, and blurred vision, perceiving things that are not there (hallucinations), over-excitability, seizures (convulsions), difficulty breathing, increased heart rate (tachycardia), inability to completely or partially empty the bladder or pass urine (urinary retention) and/or an unwanted decrease in blood pressure.

If you forget to take Vesomni

Take your next tablet of Vesomni as normal. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Vesomni

If you stop taking Vesomni, your original complaints 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 or pharmacist.

4. Possible side effects

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

The most serious side effect that has uncommonly (may affect up to 1 in 100 men) been observed during treatment with Vesomni in clinical studies is acute urinary retention, which is a sudden inability to pass urine. If you think you may have this, see a doctor straight away. You may need to stop taking Vesomni.

Allergic reactions could occur with Vesomni:

- Uncommon signs of allergic reactions can include skin rash (which can 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 on tamsulosin and very rarely with solifenacin. If angioedema occurs, Vesomni should be stopped immediately and not started again.

If you experience an allergic attack, or a severe skin reaction (e.g. blistering and peeling of the skin), you must inform your doctor immediately, and stop using Vesomni. Appropriate therapy and/or measures should be taken.

Common side effects (may affect up to 1 in 10 men)

- Dry mouth
- Constipation
- Indigestion (dyspepsia)
- Dizziness
- Blurred vision
- Tiredness (fatigue)
- Abnormal ejaculation (ejaculation disorder). This means that semen does not leave the body via the urethra, but instead goes into the bladder (retrograde ejaculation) or the ejaculation volume is reduced or absent (ejaculation failure) This phenomenon is harmless.
- Feeling sick (nausea)
- Abdominal pain

Other uncommon side effects (may affect up to 1 in 100 men)

- Sleepiness (somnolence)
- Itching (pruritus)
- Urinary tract infection, bladder infection (cystitis)
- Impaired sense of taste (dysgeusia)
- Dry eyes
- Dry nose
- Reflux disease (gastro-oesophageal reflux)
- Dry throat
- Dry skin
- Difficulty in passing urine
- Accumulation of fluid in the lower legs (oedema)
- Headache
- Fast or uneven heartbeat (palpitations)
- Feeling dizzy or weak especially when you stand up (orthostatic hypotension)
- Runny or blocked nose (rhinitis)
- Diarrhoea
- Being sick (vomiting)
- Tiredness (asthenia)

Rare side effects (may affect up to 1 in 1,000 men)

- Lodging of a large amount of hardened stool in the large intestine (faecal impaction)
- Feeling faint (syncope)
- Skin allergy that results in the swelling that occurs in the tissue just below 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 genitals (Stevens-Johnson syndrome)

Not known (frequency cannot be estimated from the available data)

- Decreased appetite
- High levels of blood potassium (hyperkalaemia) which can cause abnormal heart rhythm
- Increased pressure in the eyes (glaucoma)

- Irregular or unusual heart beat (QT prolongation, Torsade de Pointes, atrial fibrillation, arrhythmia)
- Faster heartbeat (tachycardia)
- Shortness of breath (dyspnoea)
- During an operation of the eye for cloudiness of the lens (cataract) or for increased pressure in the eye (glaucoma) the pupil (the black circle in the middle of your eye) may not increase in size as needed. Also, the iris (the coloured part of the eye) may become floppy during surgery.
- Voice disorder
- Liver disorder
- Muscle weakness
- Renal disorder
- Impaired vision
- Nose bleeds (epistaxis)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRRA Pharmacovigilance website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vesomni

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 carton or blister after EXP. The expiry date refers to the last day of that month. This medicinal product does not require any special storage conditions. Do not throw away any medicines via wastewater or 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 Vesomni contains

The active substances are 6 mg solifenacin succinate and 0.4 mg tamsulosin hydrochloride.

The other ingredients are mannitol (E421), maltose, macrogol, magnesium stearate (E470b), butylhydroxytoluene (E321), colloidal silica anhydrous (E551), hypromellose (E464), iron oxide red (E172).

What Vesomni looks like and contents of the pack

Vesomni 6 mg/0.4 mg tablets are round, red film-coated tablets, debossed with "6/0.4".

Vesomni modified release tablets are available in blister packs containing 30 tablets. The tablets are contained in an outer carton.

Manufacturer

Astellas Pharma Europe B.V., Sylviusweg 62, 2333 BE Leiden, The Netherlands.

Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder who is: PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Parallel Product Authorisation number: PPA0465/452/001

Vesomni is a registered trademark of Astellas Pharma Inc.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Greece, Ireland, Luxembourg, Slovakia, Spain, United Kingdom, The Netherlands: Vesomni

Belgium: Vesomni 6 mg/0,4 mg tabletten met geregeuleerde afgifte

Czech Republic: Urizia 6 mg/0.4 mg

Denmark, Finland, Norway, Sweden: Urizia

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