

Vecit 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 Vecit is and what it is used for
2. What you need to know before you use Vecit
3. How to use Vecit
4. Possible side effects
5. How to store Vecit
6. Contents of the pack and other information

1. What Vecit is and what it is used for

Vecit 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.

This medicine is used in men to treat moderate to severe storage and voiding symptoms of the lower urinary tract, which are caused by bladder problems and an enlarged prostate (benign prostatic hyperplasia).

Vecit is used when previous treatment with a single product for this condition did not relieve symptoms adequately.

As the prostate grows, it can lead to problems emptying your bladder (voiding symptoms) such as hesitancy (difficulty starting to urinate), difficulty urinating (poor stream), dribbling and a feeling of incomplete bladder emptying. At the same time, the bladder is also affected and contracts spontaneously at times when 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 (the tube that carries urine from the bladder to the outside of the body) and helps urination.

2. What you need to know before you use Vecit

Do not use this medicine if:

- you are allergic to solifenacin or tamsulosin or any of the other ingredients of this medicine (listed in section 6).
- you are having kidney dialysis.
- you suffer from severe kidney disease AND if, at the same time, you are being treated with medicines that may decrease the removal of solifenacin/tamsulosin from the body (for example ketoconazole, ritonavir, nelfinavir, itraconazole). Your doctor or pharmacist will have told you if this is the case.
- you have severe liver disease.
- you suffer from moderate liver disease AND if, at the same time, you are being treated with medicines that may decrease the removal of solifenacin/tamsulosin from the body (for example ketoconazole, ritonavir, nelfinavir, itraconazole). Your doctor or pharmacist will have told you if this is the case.
- you have a severe stomach or bowel condition (including toxic megacolon, a complication of 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 dizziness, lightheadedness or fainting when going to sit up or stand up due to reduced blood pressure; 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 this medicine 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 told 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 bisphosphonates (for osteoporosis), that can cause or worsen inflammation of the food pipe (oesophagitis).
 - you suffer from type of nervous disease called autonomic neuropathy.
 - you suffer from severe kidney disease.
 - you suffer from moderate liver disease.
- You will need regular medical examinations to check the development of the condition you are being treated for.
- Vecit can reduce your blood pressure, which can make you feel dizzy, light headed or rarely can make you faint when going to sit up or stand up (orthostatic hypotension). If you experience any of these symptoms, you should sit or lie down until they disappear.
- If you are having or due to have eye surgery because of cloudiness of the lens (cataract) or increased pressure in the eyes (glaucoma), please tell your eye specialist that you have previously used, are using or are planning to use Vecit. The specialist can then take precautions with medication and surgical techniques to be used. Ask your doctor whether or not you should postpone or temporarily stop taking this medicine when having eye surgery for a cataract or glaucoma.

Children and adolescents

Do not give this medicine to children and adolescents.

Other medicines and Vecit

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 solifenacin/tamsulosin is removed from the body.
- other anticholinergic medicines, as effects and side effects of both medications can be increased if you are taking two medicines of the same type.
- cholinergics, as they can reduce the effect of Vecit.
- medicines like metoclopramide and cisapride, which make the digestive system work faster (Vecit can reduce their effect).
- other alpha-blockers, as this may cause an unwanted decrease in blood pressure.
- medicines such as bisphosphonates for osteoporosis, that can cause or worsen inflammation of the food pipe (oesophagitis).

Vecit with food

This medicine can be taken with or without food, as you prefer.

Pregnancy, breast-feeding and fertility

Vecit is not for use by women.

In men, abnormal ejaculation has been reported. This means that the semen does not leave the body via the urethra (the tube that carries urine from the bladder to the outside of the body), but instead goes into the bladder or the ejaculation volume is reduced or absent. This is harmless.

Driving and using machines

Vecit 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 Vecit

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). Swallow with water by mouth with or without food, as you prefer. **Do not crush or chew the tablet.**

If you take more Vecit 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.

Do not try to make yourself sick.

Symptoms of overdose may include: dry mouth, dizziness, and blurred vision, perceiving things that are not there (hallucinations), over-excitability, seizures, difficulty breathing, increased heart rate, 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 Vecit

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

If you stop taking Vecit

If you stop taking this medicine, your original complaints may return or worsen. If you are considering stopping the treatment, always consult your doctor,

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking Vecit and tell your doctor immediately if you experience:

- allergic skin reactions such as skin rashes or hives (red, itchy, and swollen areas on the skin); red spots or ridges on the skin, inflammation and blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals
- symptoms of a serious allergic reaction including swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema). If angioedema occurs, Vecit should be stopped immediately and not started again.

The **most serious side effect** is a sudden inability to pass urine (acute urinary retention). This is an uncommon side effect observed during treatment with solifenacin/tamsulosin in clinical studies (may affect up to 1 in 100 men).

If you think you may have this, see a doctor straight away. You may need to stop treatment with this medicine.

Talk to your doctor or pharmacist if you get any of the following side effects or any possible side effects not listed in this leaflet.

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

- dry mouth
- feeling sick (nausea)
- constipation, indigestion, abdominal pain
- dizziness
- blurred vision
- tiredness (fatigue)
- abnormal ejaculation. This means that semen does not leave the body via the urethra, but instead goes into the bladder or the ejaculation volume is reduced or absent. This is harmless.

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

- sleepiness, lack of energy (asthenia)
- itching (pruritus)
- urinary tract infection, bladder infection (cystitis)
- difficulty passing urine
- reduced sense of taste
- dry eyes, dry nose
- dry throat, dry skin
- acid reflux (gastro-oesophageal reflux)
- diarrhoea, being sick (vomiting)
- swelling in the lower legs (oedema)
- headache
- fast or uneven heartbeat (palpitations)
- feeling dizzy, lightheaded or faint when you sit up or stand up (orthostatic hypotension)
- runny or blocked nose

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

Very rare side effects (may affect up to 1 in 10,000 men)

- hallucinations, confusion
- long-lasting and painful erection (usually not during sexual activity)

Frequency not known (frequency cannot be estimated from the available data)

- decreased appetite
- high levels of blood potassium which can cause abnormal heart rhythm
- increased pressure in the eyes (glaucoma)
- irregular or unusual heart beat, faster heart beat
- shortness of breath
- during an eye operation 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
- kidney disorder
- reduced vision
- nose bleeds

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 via Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Vecit

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 Vecit contains**

- The active substances are 6 mg solifenacin succinate and 0.4 mg tamsulosin hydrochloride.
- The other ingredients are: silicified microcrystalline cellulose type 90HD (microcrystalline cellulose and colloidal silicon dioxide); dibasic calcium phosphate anhydrous (E341); low-substituted hydroxypropyl cellulose (E463); magnesium stearate (E470b); macrogol 7.000.000; Cellulose, microcrystalline type 200; colloidal anhydrous silica (E551); magnesium stearate (E470b); hypromellose 6MPas (E464); macrogol 8000; iron oxide red (E172).

What Vecit looks like and contents of the pack

Vecit Modified-release Tablets are round, biconvex, red, film-coated tablets, debossed with “6 04” on one side.

Vecit Modified-release Tablets are available in PA/Aluminium/PVC/Aluminium blister packs containing 10, 20, 30, 50, 60, 90, 100 or 200 tablets.

Not all pack sizes may be marketed.

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If you are blind or partially sighted and require this leaflet in a different format, call 0800 669 6825 or contact medinfo@celixpharma.com.

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area for INDEX

Company Name	Product Name	Product Description	Version No.	
	Solifenacin Tamsulosin	Vecit 6 mg/0.4 mg Modified-release Tablets	6	
	CCR No.	Component No.	12 September 2022	
	-	CEL00047		
Reviewed / Approved by	Component	Dimension	Colors	
	PIL	180W x 560H mm	Printing Colors (Pantone/CMYK)	
	Market	Font Size (Minimum)	Technical Colors (Non-printable colors)	
	UK	9.5 pt	■ Black	
	Pharmacode	Font Type		
Sign / Date	Dummy	Helvetica Neue LT Pro		