

VESICARE®

Film-coated Tablet

Solifenacin succinate (5mg)

Solifenacin succinate (10mg)

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What VESICARE is used for

Vesicare is used to treat the symptoms of a condition called overactive bladder. These symptoms include: having a strong, sudden urge to urinate without prior warning, having to urinate frequently or wetting yourself because you could not get to the bathroom in time.

How VESICARE works

The active substance of Vesicare belongs to the group anticholinergics. These medicines are used to reduce the activity of an overactive bladder. This enables you to wait longer before having to go to the bathroom and increases the amount of urine that can be held by your bladder.

Before you use VESICARE

- When you must not use it

Do not take Vesicare

- if you have an inability to pass water or to empty your bladder completely (urinary retention)
- if you have a severe stomach or bowel condition (including toxic megacolon, a complication associated with ulcerative colitis)
- if you suffer from the muscle disease called myasthenia

gravis, which can cause an extreme weakness of certain muscles

- if you suffer from increased pressure in the eyes, with gradual loss of eye sight (glaucoma)
- if you are allergic to solifenacin or any of the other ingredients of this medicine
- if you are undergoing kidney dialysis
- if you have severe liver disease
- if you suffer from severe kidney disease or moderate liver disease and at the same time are being treated with medicines that may decrease the removal of Vesicare from the body (for example, ketoconazole). Your doctor or pharmacist will have informed you if this is the case.

Inform your doctor if you have or ever had any of the above mentioned conditions before treatment with Vesicare starts.

Vesicare is not to be used in children or adolescents under 18 years.

You should not use Vesicare if you are pregnant unless clearly necessary.

Do not use Vesicare if you are breast-feeding as solifenacin may get into your breast milk. Ask your doctor or pharmacist for advice before taking this medicine.

Vesicare contains lactose. If you have been told by your doctor that you have a rare hereditary problem of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption you should not use this medicine.

- Before you start to use it

Talk to your doctor or pharmacist before taking Vesicare

- if you have trouble emptying your bladder (bladder obstruction) or have difficulty in passing urine (e.g. a thin urine flow). Risk of accumulation of urine in the bladder (urinary retention) is much higher.
- if you have some obstruction of the digestive system (constipation)
- if 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.
- if you suffer from severe kidney disease
- if you have moderate liver disease
- if you have a stomach tear (hiatus hernia) or heartburn
- if you have a nervous disorder (autonomic neuropathy)

Inform your doctor if you have or ever had any of the above mentioned conditions before treatment with Vesicare starts. Before starting Vesicare, your doctor will assess whether there are other causes for your need to pass urine frequently (for example heart failure (insufficient pumping power of the heart) or kidney disease). If you have a urinary tract infection, your doctor will prescribe you an antibiotic (a treatment against particular bacterial infections).

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or

have recently taken or might take other medicines.

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

- other anticholinergic medicines, effects and side effects of both medications can be enhanced.
- cholinergics as they can reduce the effect of Vesicare.
- medicines, like metoclopramide and cisapride, which make the digestive system work faster.
- medicines, like ketoconazole, ritonavir, nelfinavir, itraconazole, verapamil and diltiazem, which decrease the rate at which Vesicare is broken down by the body.
- medicines like rifampicin, phenytoin and carbamazepine, as they may increase the rate at which Vesicare is broken down by the body.
- medicines such as bisphosphonates, that can cause or exacerbate inflammation of the gullet (oesophagitis).

How to use VESICARE

- How much to use

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 5 mg per day, unless your doctor told you to take 10 mg per day.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

If you stop taking Vesicare, your symptoms of overactive bladder 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 product, ask your doctor or pharmacist.

- If you forget to use it

If you forget to take a dose at the usual time, take it as soon as you remember, unless it is time to take your next dose. Never take more than one dose per day. If you are in doubt, always consult your doctor or pharmacist.

- If you use too much (overdose)

If you have taken too much Vesicare or if a child has accidentally taken Vesicare, contact your doctor or pharmacist immediately. Symptoms of overdose may include: headache, dry mouth, dizziness, drowsiness and blurred vision, perceiving things that are not there (hallucinations), over-excitability, seizures (convulsions), difficulty breathing, elevated heart rate (tachycardia), accumulation of urine in the bladder (urinary retention) and dilated pupils (mydriasis).

While you are using it

- Things you must do

Check with your doctor or pharmacist before taking your medicine and take it as prescribed by your doctor.

You should swallow the whole tablet with some liquid. It can be taken with or without food, according to your preference.

- Things you must not do

Do not crush the tablets.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- Things to be careful of

Vesicare may cause blurred vision and sometimes sleepiness or tiredness. If you suffer from any of these side effects, do not drive or operate machinery.

Side Effects

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

If you experience an allergic attack, or a severe skin reaction (e.g. blistering and peeling of the skin), you must inform your doctor or pharmacist immediately.

Angioedema (skin allergy that results in the swelling that occurs in the tissue just below the surface of the skin) with airway obstruction (difficulty in breathing) has been reported in some patients on solifenacin succinate (Vesicare). If angioedema occurs, solifenacin succinate (Vesicare) should be discontinued immediately and appropriate therapy and/or measures should be taken. Vesicare may cause the following other side effects:

Very common (may affect more than 1 in 10 people)

- dry mouth

Common (may affect up to 1 in 10 people)

- blurred vision
- constipation, nausea, indigestion with symptoms such as abdominal fullness, abdominal pain, burping, nausea, and heartburn (dyspepsia), stomach discomfort

Uncommon (may affect up to 1 in 100 people)

- urinary tract infection, bladder infection
- sleepiness, impaired sense of taste (dysgeusia)
- dry (irritated) eyes
- dry nasal passages
- reflux disease (gastro-oesophageal reflux), dry throat
- dry skin
- difficulty in passing urine
- tiredness, accumulation of fluid in the lower legs (oedema)

Rare (may affect up to 1 in 1,000 people)

- lodging of a large amount of hardened stool in the large intestine (faecal impaction)
- build up of urine in the bladder due to inability to empty the bladder (urinary retention)
- dizziness, headache
- vomiting
- itching, rash

Very rare (may affect up to 1 in 10,000 people)

- hallucinations, confusion
- allergic rash

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
- changes in the electrical activity of the heart (ECG), irregular heartbeat, feeling your heartbeat, faster heart beat
- voice disorder
- liver disorder
- muscle weakness
- renal disorder

If you get any side effects, talk to your doctor or pharmacist.

This includes any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of VESICARE

- Storage

Keep this medicine out of the sight and reach of children. Do not use Vesicare after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

There are no special precautions for storage.

- Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Vesicare 5 mg film-coated tablet: Each 5 mg tablet is a round, light-yellow tablet marked with the company logo and “150” on the same side.

Vesicare 10 mg film-coated tablet: Each 10 mg tablet is a round, light-pink tablet marked with the company logo and “151” on the same side.

- Ingredients

- Active ingredient(s)

5mg or 10mg solifenacin succinate

- Inactive ingredient(s)

Core tablet:

Maize starch, Lactose monohydrate, Hypromellose, Magnesium stearate

Film Coating:

Macrogol 8000, Talc Hypromellose, Titanium dioxide (E171)

Vesicare 5 mg: Yellow ferric oxide (E172)

Vesicare 10 mg: Red ferric oxide (E172)

- MAL number

Vesicare 5 mg Film-Coated Tablet

- MAL20091963ACZ

Vesicare 10 mg Film-Coated Tablet

- MAL20091964ACZ

Manufacturer

Delpharm Meppel B.V., Hogemaat 2, 7942 JG Meppel, The Netherlands

Product Registration Holder

Astellas Pharma Malaysia Sdn. Bhd.

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