

Package leaflet: information for the user

Vesicare™ 5 mg film-coated tablets  
Vesicare™ 10 mg film-coated tablets  
solifenacin succinate

Read the entire 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.

- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms 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.

Contents of this leaflet:

1. What is Vesicare and what is it used for?
2. When should you not take this medicine or be extra careful?
3. How to take this medicine?
4. Possible side effects
5. How to store this medicine?
6. Contents of the pack and other information

#### 1. What is Vesicare and what is it used for?

The active substance solifenacin in Vesicare belongs to the group of anticholinergics. These medicines are used to reduce the activity of an overactive bladder. This allows you to wait longer before going to the toilet and increases the amount of urine your bladder can hold.

Vesicare is used to treat symptoms of an overactive bladder. The symptoms include: a sudden strong urge to urinate without prior warning, having to urinate very frequently, or the loss of urine because you cannot reach the toilet in time.

#### 2. When should you not take this medicine or be extra careful with it?

When should you not use this medicine?

- You have urinary retention due to impaired bladder emptying.
- You suffer from a severe gastrointestinal disorder (including a certain bowel disorder associated with an acute enlargement of the colon (toxic megacolon) which can be caused by a recurrent, severe inflammation of the colon with ulceration (ulcerative colitis)).
- You suffer from a certain form of muscle weakness (myasthenia gravis).
- You suffer from increased eye pressure (glaucoma).
- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.
- You are undergoing hemodialysis.
- You have severely impaired liver function.
- You have severely impaired kidney function or moderately impaired liver function AND you are being treated with medicines that can slow down the breakdown of solifenacin

in the body (e.g., ketoconazole). Your doctor or pharmacist has informed you if this is the case.

Consult your doctor if you have or have ever had any of the above conditions before you start using Vesicare.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before taking this medicine.

- if you have impaired bladder emptying (= bladder obstruction) or have problems urinating (for example, if you urinate with a weak stream). You are at risk of urine accumulating in the bladder (urinary retention).
- if you have a blockage of the gastrointestinal tract (constipation).
- if you have an increased risk of delayed gastrointestinal emptying. Your doctor has informed you if this is the case.
- if you have severely impaired kidney function.
- if you have moderately impaired liver function.
- if you have a hiatal hernia or heartburn.
- if you have autonomic neuropathy (a disorder of the autonomic nervous system).

Children and adolescents up to 18 years

Vesicare should not be used by children under 18 years of age.

Consult your doctor if any of the above warnings apply to you, or have applied in the past.

Before you can start treatment with Vesicare, your doctor will first investigate if there are other causes of frequent urination (e.g., heart failure (insufficient pumping power of the heart) or kidney disease). If you have a urinary tract infection, your doctor will prescribe an antibiotic (a medicine against certain bacterial infections).

Are you taking any other medicines?

Are you taking any other medicines besides Vesicare, have you done so recently, or is there a possibility that you will take other medicines in the near future? If so, tell your doctor or pharmacist.

It is especially important to consult your doctor if you are taking any of the following medicines:

other anticholinergic medicines, as the effects and side effects of both medicines may be enhanced.

cholinergic medicines that can reduce the effect of Vesicare.

medicines, such as metoclopramide and cisapride, that increase gastrointestinal activity. Vesicare can reduce the effect of these medicines.

medicines, such as ketoconazole, ritonavir, nelfinavir, itraconazole, verapamil, and diltiazem, that can slow down the breakdown of Vesicare in the body.

medicines, such as rifampicin, phenytoin, and carbamazepine, that may accelerate the breakdown of Vesicare in the body.

medicines such as bisphosphonates, which can cause or worsen inflammation of the esophagus (esophagitis).

What should you pay attention to with food and drink?

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

### Pregnancy and breastfeeding

It is recommended not to use Vesicare during pregnancy unless absolutely necessary. Do not use Vesicare if you are breastfeeding, as solifenacin may pass into breast milk.

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

### Driving and using machines

Vesicare can cause blurred vision and sometimes drowsiness or fatigue. If you experience these side effects, do not operate machines that require alertness and do not drive vehicles.

Vesicare contains lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## 3. How to take this medicine?

### Instructions for proper use

Always use this medicine exactly as your doctor has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

You should swallow the tablet whole with some liquid. The tablet can be taken with or without food, according to your preference. Do not crush the tablets.

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

### Have you taken too much of this medicine?

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. Symptoms of severe overdose may include seeing things that are not there (hallucinations), severe agitation, seizures/convulsions, breathing problems, rapid heartbeat (tachycardia), accumulation of urine in the bladder (urinary retention), and pupil dilation (mydriasis).

### Have you forgotten to take this medicine?

If you forget to take a dose at the usual time, take it as soon as you remember, unless it is time for your next dose. Do not take a double dose to make up for a forgotten tablet. Always consult your doctor or pharmacist if in doubt.

### If you stop taking this medicine

If you stop using Vesicare, your symptoms of overactive bladder may return or worsen. Always consult your doctor if you are considering stopping.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

## 4. Possible side effects

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

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

Angioedema (skin allergy resulting in swelling of the tissue just below the skin surface) with airway obstruction (breathing difficulties) 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.

The following side effects could occur with the use of Vesicare:

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 a full feeling in the upper abdomen, pain in the (lower) abdomen, belching, heartburn (dyspepsia), stomach problems

Uncommon (may affect up to 1 in 100 people)

urinary tract infection, cystitis

drowsiness

taste disorder (dysgeusia)

dry (irritated) eyes

dry nasal mucosa

reflux of (burning) stomach acid (gastroesophageal reflux)

dry throat

dry skin

problems with urination

fatigue

fluid retention in the lower legs (peripheral edema)

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

accumulation of a large amount of hard stool in the colon (fecal impaction)

retention of urine in the bladder due to impaired bladder emptying (urinary retention)

dizziness, headache

vomiting

itching, skin rash

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

perceptions of things that are not there (hallucinations), confusion

skin rash with severe itching and welts (hives or urticaria)

Not known (cannot be determined from the available data)

decreased appetite, increased potassium levels in the blood that can cause an abnormal heart rhythm

increased pressure in the eyes

changes in the electrical activity of the heart (ECG), irregular heartbeat, feeling your heartbeat (palpitations), accelerated heartbeat  
voice disorders  
liver disorders  
muscle weakness  
kidney disorders

#### Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: [www.lareb.nl](http://www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

#### 5. How should you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. This can be found on the carton and on the blister pack after 'EXP'. It includes a month and a year. The last day of that month is the expiry date.

There are no special storage conditions for this medicine. For the bottle packaging: after the bottle is first opened, the tablets can be stored for another 6 months. Keep the bottle tightly closed.

#### 6. Contents of the pack and other information

What substances are in this medicine?

- The active substance in this medicine is solifenacin succinate 5 mg or 10 mg
- The other substances in this medicine are corn starch, lactose, hypromellose (E464), magnesium stearate, macrogol, talc, titanium dioxide (E171), iron oxide (E172)

What does Vesicare look like and what is in a pack?

Vesicare 5 mg tablets are round, light yellow tablets marked with the company logo and the code '150' on the same side.

Vesicare 10 mg are round, light pink tablets marked with the company logo and the code '151' on the same side.

Vesicare tablets are available in blister packs of 3, 5, 10, 20, 30, 50, 60, 90, or 100 tablets or in HDPE bottles with PP cap of 100 tablets.

Not all pack sizes mentioned are marketed.

Marketing authorization holder

Astellas Pharma Europe B.V.

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Manufacturer

Delpharm Meppel B.V.

Hogemaat 2  
7942 JG Meppel  
Netherlands

RVG numbers  
RVG 29151 (Vesicare 5 mg)  
RVG 29152 (Vesicare 10 mg)

This medicine is registered in EEA member states under the following names:  
Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece,  
Hungary, Iceland, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland,  
Portugal, Sweden, Slovenia, Slovakia, Spain, and United Kingdom: Vesicare  
Italy: Vesiker  
Germany: Vesikur  
Ireland: Vesitirim

This leaflet was last approved in April 2024.