Package leaflet: Information for the user

Vesicare 1 mg/ml oral suspension

solifenacin succinate

Read all of this leaflet carefully before you start taking 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 Vesicare is and what it is used for

The active substance of Vesicare belongs to the group of 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.

Vesicare is used to:

- treat the symptoms of a condition called overactive bladder in adults.
  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.

- treat a condition called neurogenic detrusor overactivity in children aged 2 to 18 years. Neurogenic detrusor overactivity is a condition in which involuntary bladder contractions occur due to a condition that you are born with or injury to the nerves which control the bladder. If left untreated, neurogenic detrusor overactivity may lead to damage to your bladder and/or kidneys.
  Vesicare is used to increase the amount of urine your bladder can hold and reduce urine leakage.

2. What you need to know before you take Vesicare

Do not take Vesicare if you:
- have an inability to pass water or to empty your bladder completely (urinary retention) and you do not practice clean intermittent catheterization (CIC);
- have a severe stomach or bowel condition (including toxic megacolon, a complication associated with ulcerative colitis);
- suffer from the muscle disease called myasthenia gravis, which can cause an extreme weakness of certain muscles;
- suffer from increased pressure in the eyes, with gradual loss of eye sight (glaucoma);
- are allergic to solifenacin or any of the other ingredients of this medicine (listed in Section 6);
- are undergoing kidney dialysis;
- have severe liver disease;

- 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.

Warnings and precautions
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) and you do not practice clean intermittent catheterization (CIC). In such a case the risk of accumulation of urine in your bladder (urinary retention) is much higher;
- have some obstruction of the digestive system (constipation);
- are at risk of your digestive system slowing down (stomach and bowel movements). Your doctor will have informed you if this is the case;
- suffer from any condition which results in alterations of your heart rhythm, especially an abnormality known as QT prolongation;
- suffer from severe kidney disease;
- have moderate liver disease;
- have a stomach tear (hiatus hernia) or heartburn;
- 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).

Children and adolescents
Vesicare is not to be used in children under 2 years of age for treatment of neurogenic detrusor overactivity. Vesicare is not to be used in children under 18 years of age for treatment of overactive bladder.

Other medicines and Vesicare
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. Vesicare can reduce their effect.
- 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).

Vesicare with food and drink
Vesicare oral suspension should not be taken together with food and/or other drinks than water. Take a glass of water after you have taken a dose. See Section 3. If you have taken accidently the suspension with food and/or drinks, you might experience a bitter taste and a feeling of numbness in your mouth.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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.

Driving and using machines
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.

Vesicare oral suspension contains ethanol: This product contains small amounts of ethanol (alcohol), less than 100 mg per maximum daily dose (10 ml Vesicare oral suspension). Ethanol originates from the natural orange flavour.

Vesicare oral suspension contains methyl parahydroxybenzoate and propyl parahydroxybenzoate: This may cause an allergic reaction (this might not happen straight away). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

If you get Vesicare oral suspension in your eyes: rinse and clean your eyes thoroughly with water.

3. How to take Vesicare

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

Take this medicine by mouth, once daily. You can take this medicine before or after a meal. Drink a glass of water after you have taken a Vesicare dose. Do not take this medicine together with food and/or other drinks. If you have accidently taken the suspension with food and/or other drinks, you might experience a bitter taste and a feeling of numbness in your mouth.

Adults with overactive bladder
The usual dose is 5 mg (5 ml) per day, unless your doctor told you to take 10 mg (10 ml) per day. If you need to take a dose of 5 mg, you should use a 5 ml oral syringe. If you need to take a dose of 10 mg, you should use a 10 ml oral syringe.

Children and adolescents (age 2 to 18 years) with neurogenic detrusor overactivity
Your doctor will tell you which dose you/your child should take. Your doctor will calculate the correct dose for a patient depending on his or her body weight. Your pharmacist and doctor will tell you which syringe you should use. You should carefully follow their instructions.

How to take the Vesicare dose using an oral syringe

Use the oral syringe and adaptor provided by the pharmacist or healthcare provider to make sure you measure the right amount

1. Shake the bottle at least 20 times prior to each administration
2. Before first use of a bottle, remove the cap and attach the adaptor to the bottle according to the instructions by your pharmacist or healthcare provider
3. Insert the tip of the oral syringe into the adaptor until it is firmly in place
4. Carefully turn the bottle and syringe upside down
5. Pull back the plunger of the syringe to withdraw the amount prescribed by your doctor from the inverted bottle
6. Leave the syringe in place and turn the bottle upright, ensuring the plunger does not move. Gently remove the syringe from the adaptor and confirm the appropriate dose has been measured
7. Slowly dispense the oral suspension directly into the patient's mouth until all of the liquid medicine is given
8. In case of a press-in adaptor, leave the bottle adaptor in the neck of the bottle or follow the instructions by your pharmacist or healthcare provider

9. Close the bottle with the cap
10. Remove the plunger from the barrel of the syringe by gently pulling. Rinse the plunger and barrel with water and dry prior to storing the oral syringe

If you take more Vesicare than you should
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).

If you forget to take Vesicare
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 stop taking Vesicare
If you stop taking Vesicare, your symptoms of your underlying bladder disease 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.

4. Possible side effects

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

Stop taking Vesicare and seek medical help immediately if you notice any of the following side effects:

If you experience an allergic attack (a sudden and rapid side effect consisting of generalized itching, hives, swelling, difficulty breathing and/or other allergic reactions, called anaphylaxis), or a severe skin reaction (e.g. blistering and peeling of the skin).

If you experience an 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). Angioedema has been reported in some patients on Vesicare.

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

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 (for details see below). By reporting side effects you can help provide more information on the safety of this medicine.

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Pharmaceutical Services
Ministry of Health
CY-1475 Nicosia
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Website: www.moh.gov.cy/phs

5. How to store Vesicare

Keep this medicine out of the sight and reach of children.

Do not use Vesicare after the expiry date which is stated on the label, carton or bottle after EXP. The expiry date refers to the last day of that month.

Store this medicine in the original bottle in order to protect from light. This medicinal product does not require any special temperature storage conditions. After first opening of the bottle, the suspension can be stored for 28 days.

Discard any medicine remaining after 28 days after opening of the bottle.

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.

6. Contents of the pack and other information

What Vesicare contains

- The active substance is solifenacin succinate 1 mg per ml suspension.
- The other ingredients are polacrilin potassium, methylhydroxybenzoate (E218), propylhydroxybenzoate (E216), propylene glycol (E1520), simethicone emulsion 30% (consisting of simethicone, polyethylene glycol sorbitan tristearate (E436), methylcellulose (E461), polyethylene glycol stearate, glycerides, xanthan gum (E415), benzoic acid (E210), sorbic acid (E200), sulphuric acid (E513) and water), carbomer, xylitol (E967), acesulfame potassium (E950), natural orange flavour (consisting of orange essential oils, natural flavouring substances, ethanol, propylene glycol (E1520), butylated hydroxyanisol (E320) and water), sodium hydroxide, purified water.

What Vesicare looks like and contents of the pack

Vesicare suspension is a white to off-white coloured aqueous, homogeneous suspension with an orange flavour.
Vesicare suspension is supplied in an amber polyethylene terephthalate (PET) bottle of 150 ml with a polyethylene (PE) screw-cap.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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Manufacturer

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

Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Luxemburg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, Slovakia, Spain and United Kingdom: Vesicare
Italy: Vesiker
Germany: Vesikur
Ireland: Vesitirim

This leaflet was last revised in February 2018.