PACKAGE LEAFLET: INFORMATION FOR THE USER

VESICARE® 10mg FILM-COATED TABLETS
(solifenacin succinate)

The name of your medicine is Vesicare 10mg film-coated tablets but will be referred to as Vesicare throughout the following leaflet.

Information about other strength i.e. Vesicare 5mg Film-Coated Tablets also may be present in this leaflet

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. 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.

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)
- 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 (listed in section 6)
- 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.

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). 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).

Children and adolescents

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

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).

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 can be taken with or without food, depending on your preference.

Pregnancy and breast-feeding

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.

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 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.

3. How to take Vesicare

Instructions for proper use

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

You should swallow the whole tablet with some liquid. It 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 told you to take 10 mg per day.

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 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.

4. Possible 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

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 the 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 Vesicare

- **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**
- There are no special precautions for storage.
- Do not take this medicine after the expiry date shown on the carton after EXP. The expiry date refers to the last day of that month.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of via household wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Vesicare contains

- Each tablet contains 10mg solifenacin succinate equivalent to 7.5 mg solifenacin.
- The other ingredients are maize starch, lactose, hypromellose (E464), magnesium stearate, macrogol, talc, titanium dioxide (E171) and red iron oxide (E172).

What Vesicare looks like and contents of the pack

Vesicare is round, light pink film-coated tablet marked with the company logo and the code “151” on the same side and plain on the other.

Vesicare is supplied in blister packs of 30 tablets.

Product Licence holder

Procured from within the EU and repackaged by the Product Licence holder: S&M Medical Ltd, Chemilines House, Alperton Lane, Wembley, HA0 1DX.

Manufacturer

This product is manufactured by

- Astellas Pharma Europe BV, Hogemaat 2, 7942 JG Meppel, Netherlands or
- Astellas Pharma Europe BV, Sylviusweg 62, 2333 BE Leiden, Netherlands.

POM PL : 19488/1683

Leaflet revision date: 22 July 2021

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PACKAGE LEAFLET: INFORMATION FOR THE USER

SOLIFENACIN SUCCINATE 10mg FILM-COATED TABLETS

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What is in this leaflet

1. What Solifenacin Tablets is and what it is used for

The active substance of Solifenacin Tablets 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.

Solifenacin Tablets 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.

2. What you need to know before you take Solifenacin Tablets

Do not take Solifenacin Tablets

- if you have an inability to pass water or to empty your bladder completely (urinary retention)
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- 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 (listed in section 6)
- 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 Solifenacin Tablets 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 Solifenacin Tablets starts.

Warnings and precautions

Talk to your doctor or pharmacist before taking Solifenacin Tablets

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