

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using VESICARE?

VESICARE contains the active ingredient solifenacin succinate. VESICARE is used to treat the symptoms of overactive bladder.

For more information, see Section [1. Why am I using VESICARE?](#) in the full CMI.

### 2. What should I know before I use VESICARE?

Do not use if you have ever had an allergic reaction to VESICARE or any of the ingredients listed at the end of the CMI.

There are a number of circumstances in which a person should not use this medicine or may need to use caution. It is important to understand if these apply to you before taking VESICARE (see Section [2. What should I know before I use VESICARE?](#) in the full CMI for more details)

### 3. What if I am taking other medicines?

Some medicines may interfere with VESICARE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use VESICARE?

- The usual dose is 5 to 10 mg of VESICARE once a day. Your doctor will decide the most suitable dose for you.
- Talk to your doctor or pharmacist if you feel that the effect of VESICARE is too strong or too weak.

More instructions can be found in Section [4. How do I use VESICARE?](#) in the full CMI.

### 5. What should I know while using VESICARE?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Before starting any new medicine, tell your doctor or pharmacist that you are taking VESICARE.</li><li>• Tell all the doctors, dentists and pharmacists who are treating you that you are taking VESICARE.</li><li>• If you become pregnant while taking VESICARE, tell your doctor.</li><li>• Visit your doctor regularly so they can check on your progress.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking VESICARE, or lower the dose, without checking with your doctor.</li><li>• Do not use VESICARE to treat any other conditions unless your doctor tells you to.</li><li>• Do not give VESICARE to anyone else, even if they have the same condition as you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how VESICARE affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your tablets in a cool dry place where the temperature stays below 30°C.</li><li>• Do not store VESICARE or any other medicine in the bathroom or near a sink.</li><li>• Do not leave VESICARE in the car or on window sills.</li><li>• Heat and dampness can destroy some medicines.</li></ul>

For more information, see Section [5. What should I know while using VESICARE?](#) in the full CMI.

### 6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The most common and serious side effects are allergic reactions including swelling of the face, lips, throat or tongue, difficulty breathing; chest pain or tightness; swelling of the feet or legs; changes in electrical activity of the heart (ECG), irregular heartbeat (Torsade de Points).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# VESICARE®

Active ingredient(s): *solifenacin succinate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using VESICARE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VESICARE.**

**Where to find information in this leaflet:**

- [1. Why am I using VESICARE?](#)
- [2. What should I know before I use VESICARE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use VESICARE?](#)
- [5. What should I know while using VESICARE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using VESICARE?

VESICARE contains the active ingredient **solifenacin succinate**.

VESICARE is used to treat the symptoms of **overactive bladder**. These symptoms include needing to rush to the toilet to urinate without warning, needing to urinate frequently, or wetting yourself because you did not get to the toilet in time.

VESICARE belongs to a group of medicines called anticholinergic medicines. It works by acting on specialised cells to reduce the activity of your bladder and help you control your bladder.

Your doctor may have prescribed VESICARE for another reason. Ask your doctor if you have any questions about why VESICARE has been prescribed for you.

VESICARE is available only with a doctor's prescription.

There is no evidence that VESICARE is addictive.

### 2. What should I know before I use VESICARE?

#### Warnings

**Do not use VESICARE if:**

- you are allergic to solifenacin, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath. Always check the ingredients to make sure you can use this medicine.
- you suffer from urinary retention (inability to urinate or empty your bladder completely)
- you are undergoing haemodialysis
- you have severe kidney disease or moderate liver disease and are also taking medicines that can decrease the removal of VESICARE from the body (see Section 3. What if I am taking other medicines?)
- you have severe liver disease
- you have uncontrolled glaucoma (high pressure in the eyes, with gradual loss of eye sight)

- you have myasthenia gravis, a disease of the muscles causing drooping eyelids, double vision, difficulty in speaking or swallowing and sometimes muscle weakness in the arms or legs
- you have a blocked gastro-intestinal tract or other gastro-intestinal disorders such as ulcerative colitis or toxic megacolon.
- **the expiry date (Exp.) printed on the pack has passed.**
- **the packaging is torn or shows signs of tampering.**

**Check with your doctor if you:**

- **are allergic to any other medicines, foods, dyes or preservatives.**

**Do not give VESICARE to children.**

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

Tell your doctor if you are pregnant.

VESICARE may affect your developing baby if you take it during pregnancy. Your doctor will decide if you should take it.

Do not take VESICARE if you are breastfeeding.

**Tell your doctor if you have, or have had, any medical conditions, especially the following:**

- low potassium levels or a family history of heart rhythm problems. VESICARE may have an effect on the electrocardiogram (ECG - a heart tracing) and may add to the effect of other medicines on the ECG. You should advise your doctor of any other medicines you are currently taking, particularly those affecting the heart rhythm. Your doctor may wish to perform an ECG if you have any risks of having an abnormal heart rhythm.
- blockage to your bladder that causes difficulty urinating
- obstruction of the digestive system (constipation)
- glaucoma (high pressure in the eyes, with gradual loss of eye sight)
- hiatus hernia or gastric reflux or are currently being treated with some medicines (such as bisphosphonates) which may make your reflux worse
- autonomic neuropathy, a nerve problem which sometimes occurs with diabetes and can lead to diarrhoea, impotence or low blood pressure
- severe kidney disease
- moderate liver disease.

**If you have not told your doctor about any of the above, tell him/her before you start taking VESICARE.**

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by VESICARE, or may affect how well it works.

Some medicines can slow down the removal of VESICARE from the body. If you are taking any of the following, 5 mg a day is the maximum recommended dosage:

- some antifungal medicines such as ketoconazole, itraconazole
- ritonavir and nelfinavir, medicines to treat HIV infection.

**If you are taking any of the above medicines and you also have severe kidney disease or moderate liver disease, you should not take VESICARE.**

**If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.**

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking VESICARE.

## 4. How do I use VESICARE?

### How much to take

- The usual dose is 5 to 10 mg of VESICARE once a day. Your doctor will decide the most suitable dose for you.
- Talk to your doctor or pharmacist if you feel that the effect of VESICARE is too strong or too weak.

**Follow all directions given to you by your doctor and pharmacist carefully.**

### When to take VESICARE

- Try and take VESICARE at the same time each day.

### How to take VESICARE

- VESICARE is taken by mouth. It can be taken with or without food.
- **Swallow the tablets whole with a glass of water.**
- **Do not crush or chew the tablets.**
- If you crush or chew VESICARE tablets, they may not work as well.

### If you forget to take VESICARE

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.**

**Do not take a double dose to make up for the dose you missed.**

**If you are not sure what to do, ask your doctor or pharmacist.**

### How long to take VESICARE for

To properly control your condition, VESICARE must be taken every day.

**Keep taking VESICARE for as long as your doctor recommends.**

### If you use too much VESICARE (overdose)

If you think that you have used too much VESICARE, you may need urgent medical attention.

### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using VESICARE?

### Things you should do

**Before starting any new medicine, tell your doctor or pharmacist that you are taking VESICARE.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking VESICARE.**

**If you become pregnant while taking VESICARE, tell your doctor.**

**Visit your doctor regularly so they can check on your progress.**

### Things you should not do

- **Do not stop taking VESICARE, or lower the dose, without checking with your doctor.**
- **Do not use VESICARE to treat any other conditions unless your doctor tells you to.**
- **Do not give VESICARE to anyone else, even if they have the same condition as you.**

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how VESICARE affects you.**

VESICARE may cause dizziness in some people

**Do not drive or operate machinery if you suffer from any of these side effects.**

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

### Looking after your medicine

- **Keep it where young children cannot reach it.**
- A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.
- **Keep your tablets in a cool dry place where the temperature stays below 30°C.**
- **Do not store VESICARE or any other medicine in the bathroom or near a sink.**
- **Do not leave VESICARE in the car or on window sills.**

Heat and dampness can destroy some medicines.

### Getting rid of any unwanted medicine

**If your doctor tells you to stop taking VESICARE, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.**

## 6. Are there any side effects?

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking VESICARE.**

Like all other medicines, VESICARE may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

**Ask your doctor or pharmacist to answer any questions you may have.**

#### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• nausea, vomiting</li> <li>• constipation</li> <li>• indigestion</li> <li>• heartburn (dyspepsia)</li> <li>• stomach discomfort</li> <li>• urinary tract infection, bladder pain</li> <li>• difficulty passing urine, inability to empty the bladder</li> <li>• urgent need to urinate</li> <li>• blurred vision</li> <li>• inability to empty the bladder</li> <li>• dry eyes</li> <li>• tiredness</li> <li>• muscle weakness</li> <li>• accumulation of fluid (swelling) in the lower limbs (oedema)</li> <li>• dizziness</li> <li>• sore / dry throat</li> <li>• cough</li> <li>• headache</li> <li>• sleepiness</li> <li>• hallucination</li> <li>• confusion</li> <li>• depression</li> <li>• fast heartbeat</li> <li>• palpitations</li> <li>• skin reactions such as rash, itching or hives.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

#### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• allergic reactions including swelling of the face, lips, throat or tongue, difficulty breathing</li> <li>• chest pain or tightness</li> <li>• swelling of the feet or legs</li> <li>• changes in electrical activity of the heart (ECG), irregular heartbeat (Torsade de Points)</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p> <p><b>Tell your doctor as soon as possible if you notice any of the following</b></p>

**Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.**

**Some of these side effects (for example, changes in electrical activity of the heart or liver function) can only be found when your doctor does tests from time to time to check your progress.**

#### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

#### What VESICARE contains

<b>Active ingredient (main ingredient)</b>	solifenacin succinate <ul style="list-style-type: none"> <li>• each VESICARE 5 tablet contains 5 mg solifenacin succinate</li> <li>• each VESICARE 10 tablet contains 10 mg solifenacin succinate.</li> </ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• maize starch</li> <li>• lactose monohydrate</li> <li>• hypromellose (E464)</li> <li>• magnesium stearate</li> <li>• macrogol</li> <li>• talc</li> <li>• titanium dioxide</li> <li>• iron oxide yellow (5 mg tablets only)</li> <li>• iron oxide red (10 mg tablets only).</li> </ul> <p>Vesicare contains sugars as lactose</p>

**Do not take this medicine if you are allergic to any of these ingredients.**

#### What VESICARE looks like

VESICARE comes in two strengths of tablets:

- VESICARE 5 mg tablets (AUST R 117217) are round light-yellow tablets marked with logo and "150".
- VESICARE 10 mg tablets (AUST R 117227) are round light-pink tablets marked with logo and "151".

Each blister pack contains 30 tablets.

#### Who distributes VESICARE

Astellas Pharma Australia Pty Ltd  
Suite 2.01, 2 Banfield Road  
Macquarie Park NSW 2113

Medical Information:

1800 751 755

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