

# SOLIFENACIN VIATRIS

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## 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.

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### 1. Why am I using SOLIFENACIN VIATRIS?

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

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

### 2. What should I know before I use SOLIFENACIN VIATRIS?

Do not use if you have ever had an allergic reaction to SOLIFENACIN VIATRIS 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 SOLIFENACIN VIATRIS. For more

information, see Section [2. What should I know before I use SOLIFENACIN VIATRIS?](#) in the full CMI.

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

Some medicines may interfere with SOLIFENACIN VIATRIS 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 SOLIFENACIN VIATRIS?**

- The usual dose is 5 mg to 10 mg of SOLIFENACIN VIATRIS 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 SOLIFENACIN VIATRIS is too strong or too weak.

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

### **5. What should I know while using SOLIFENACIN VIATRIS?**

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using SOLIFENACIN MYLAN.</li></ul>
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	<ul style="list-style-type: none"> <li>● Tell all the doctors, dentists and pharmacists who are treating you that you are taking SOLIFENACIN VIATRIS.</li> <li>● Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.</li> <li>● Visit your doctor regularly so they can check on your progress.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● Do not stop taking your medicine or change the dosage without checking with your doctor.</li> <li>● Do not use SOLIFENACIN VIATRIS to treat any other conditions unless your doctor tells you to.</li> <li>● Do not give SOLIFENACIN VIATRIS to anyone else, even if they have the same condition as you</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● Be careful driving or operating machinery until you know how</li> </ul>

	SOLIFENACIN VIATRIS affects you.
<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 25°C.</li> <li>• Do not store SOLIFENACIN VIATRIS or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.</li> <li>• Heat and dampness can destroy some medicines.</li> </ul>

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

## 6. Are there any side effects?

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.



# SOLIFENACIN VIATRIS

Active ingredient(s): *solifenacin succinate*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using SOLIFENACIN VIATRIS. **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 SOLIFENACIN VIATRIS.**

Where to find information in this leaflet:

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

## 1. Why am I using SOLIFENACIN VIATRIS?

**SOLIFENACIN VIATRIS contains the active ingredient solifenacin succinate.** SOLIFENACIN VIATRIS belongs to a group of medicines called anticholinergic medicines. It works by acting on

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specialised cells to reduce the activity of your bladder and help you control your bladder.

**SOLIFENACIN VIATRIS 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.

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

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

This medicine is not addictive.

## **2. What should I know before I use SOLIFENACIN VIATRIS?**

### **Warnings**

**Do not use SOLIFENACIN VIATRIS 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 rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body 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.

- suffer from urinary retention (inability to urinate or empty your bladder completely)
- are undergoing haemodialysis
- have severe kidney disease or moderate liver disease and are also taking medicines that can decrease the removal of SOLIFENACIN VIATRIS from the body (see Section 3. What if I am taking other medicines?)
- have severe liver disease
- have uncontrolled glaucoma (high pressure in the eyes, with gradual loss of eye sight)
- have myasthenia gravis, a disease of the muscles causing drooping eyelids, double vision, difficulty in speaking or swallowing and sometimes muscle weakness in arms or legs.
- have a blocked gastro-intestinal tract or other gastro-intestinal disorders such as ulcerative colitis or toxic megacolon.

**Do not give SOLIFENACIN VIATRIS to children.**

**Check with your doctor if you:**

- have allergies to any other medicines, foods, preservatives or dyes.

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 or plan to become pregnant or are breastfeeding. Your doctor can discuss with you the risks and benefits involved.

Do not take SOLIFENACIN VIATRIS if you are breastfeeding.

### **Tell your doctor if you have or have had any of the following medical conditions:**

- low potassium levels or a family history of heart rhythm problems. SOLIFENACIN VIATRIS may have an effect on the electro-cardiogram (ECG - a heart tracing) and may add to the effect of other medicines on the ECG. You should advise your doctor 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 SOLIFENACIN VIATRIS.

### **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 interfere with SOLIFENACIN VIATRIS and affect how it works.**

Some medicines can slow down the removal of SOLIFENACIN VIATRIS 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
- ciclosporin, a medicine that suppresses the immune system
- some antibiotic medicines such as erythromycin and clarithromycin.

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

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SOLIFENACIN VIATRIS.**

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

## **4. How do I use SOLIFENACIN VIATRIS?**

### **How much to take**

- The usual dose is 5 mg to 10 mg of SOLIFENACIN VIATRIS 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 SOLIFENACIN VIATRIS is too strong or too weak.
- Follow all directions given to you by your doctor and pharmacist carefully.

### **When to take SOLIFENACIN VIATRIS**

- Try and take SOLIFENACIN VIATRIS at the same time each day.

## **How to take SOLIFENACIN VIATRIS**

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

## **If you forget to take SOLIFENACIN VIATRIS**

**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 it as soon as you remember, and then go back to taking your medicine 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 SOLIFENACIN VIATRIS for**

- To properly control your condition, SOLIFENACIN VIATRIS must be taken every day.
- Continue taking SOLIFENACIN VIATRIS for as long as your doctor tells you to.

## **If you use too much SOLIFENACIN VIATRIS**

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

### **You should immediately:**

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 SOLIFENACIN VIATRIS?**

### **Things you should do**

- **If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking SOLIFENACIN VIATRIS.**
- **Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.**
- **If you become pregnant while taking this medicine, tell your doctor immediately.**
- **Keep all of your doctor's appointments so that your progress can be checked.**

## **Things you should not do**

- Do not stop taking your medicine or change the dosage without checking with your doctor.
- Do not take SOLIFENACIN VIATRIS to treat any other complaints unless your doctor tells you to.
- Do not give your medicine 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 SOLIFENACIN VIATRIS affects you.**

SOLIFENACIN VIATRIS may cause dizziness in some people, sometimes cause blurred vision and less frequently drowsiness and fatigue.

**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 your tablets in the pack or bottle until it is time to take them. If you take the tablets pack or bottle they may not keep well.
- Store below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**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.

## **Getting rid of any unwanted medicine**

If your doctor tells you to stop taking this medicine, if you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **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 SOLIFENACIN VIATRIS.**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

**Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● dry mouth</li> <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> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>



<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <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>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<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</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>Stop taking SOLIFENACIN VIATRIS and tell your doctor as soon as possible if you experience or if</b></p>

<b>Serious side effects</b>	<b>What to do</b>
heartbeat (Torsade de Points).	<b>you notice any of the following.</b>

Other side effects not listed here may occur in some people. **Tell your doctor or pharmacist if you notice anything else that may be 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 SOLIFENACIN VIATRIS contains

<b>Active ingredient (main ingredient)</b>	solifenacin succinate
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• lactose monohydrate</li><li>• maize starch</li><li>• hypromellose</li><li>• purified talc</li><li>• magnesium stearate</li><li>• OPADRY complete film coating system 03H520077 yellow ( ARTG PI No: 109790) for 5 mg tablets</li><li>• OPADRY complete film coating system 03H540078 ( ARTG PI No: 109766) pink for 10 mg tablets.</li></ul>
<b>Potential allergens</b>	sugars as lactose and trace quantities of sulfites.

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

## What SOLIFENACIN VIATRIS looks like

- SOLIFENACIN VIATRIS 5 mg tablets (AUST R 268512) are yellow film-coated, round, biconvex tablet debossed with M one side of the tablet and SF over 5 on the other side.
- SOLIFENACIN VIATRIS 10 mg tablets (AUST R 268515) are pink film-coated, round, biconvex tablet debossed with M on one side of the tablet and SF over 10 on the other side.

SOLIFENACIN VIATRIS is available in bottles containing 30 tablets.

## Who distributes SOLIFENACIN VIATRIS

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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