

VESICARE[®]

5 mg and 10 mg film coated tablets

Solifenacin succinate

What is in this leaflet

This leaflet answers some common questions about Vesicare.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Vesicare is used for

This medicine 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.

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

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 purpose.

This medicine is not addictive.

It is available only with a doctor's prescription.

Before you take Vesicare

When you must not take it

Do not take Vesicare if you have an allergy to:

- any medicine containing solifenacin succinate
- any of the ingredients listed at the end of this leaflet

Symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take Vesicare if you:

- suffer from an inability to urinate or empty your bladder completely (urinary retention)
- have high pressure in the eyes, with gradual loss of eye sight (uncontrolled glaucoma)
- have the muscle condition called myasthenia gravis, which can cause extreme weakness in certain muscles. Symptoms include drooping eyelids, double vision, difficulty in speaking or swallowing and sometimes muscle weakness in the arms or legs
- suffer from a severe stomach or bowel condition (including toxic megacolon, a complication associated with ulcerative colitis)
- are undergoing kidney dialysis (haemodialysis)
- have severe liver disease
- have severe kidney disease or moderate liver disease and are also taking medicines that can decrease the removal of Vesicare from the body (see Taking Other Medicines)

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- blockage to your bladder which causes you to have difficulty urinating
- an obstruction in your digestive system
- are at risk of your digestive system slowing down
- severe kidney disease
- moderate liver disease

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.

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

Taking other medicines

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

Some medicines interfere with each other. These include:

- medicines that can decrease the removal of Vesicare from the body. These include some antifungal medicines such as ketoconazole and itraconazole and some medicines used to treat HIV infection such as ritonavir and nelfinavir.
- other anticholinergic medicines, which are medicines used to prevent travel sickness, relieve stomach cramps, treat overactive bladder or Parkinson's Disease.
- cholinergic receptor agonists such as pilocarpine, used in the treatment of glaucoma.
- medicines which make the digestive system work faster, such as metoclopramide and cisapride.

These medicines may be affected by Vesicare or may affect how well it works. You may need different amounts of your medicines or you may need to take different medicines.

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

How to take Vesicare

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The usual dose is one 5mg or one 10mg tablet once a day. Your doctor will tell you which dose is suitable for you.

Talk to your doctor or pharmacist if you have the impression that the effect of Vesicare is too strong or too weak.

How to take it

Swallow the tablets whole with a full glass of water.

Do not crush or chew the tablets.

If you crush or chew the tablets they may not work as well.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine with or without food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

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

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

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much Vesicare. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Vesicare

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Vesicare.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you become pregnant while using this medicine, tell your doctor immediately.

Things you must not do

Do not use Vesicare 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.

Do not stop using your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen.

Things to be careful of

Be careful driving or operating machinery until you know how Vesicare tablets affect you.

This medicine may cause blurred vision, drowsiness and tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous if you have blurred vision, feel tired or drowsy.

Side effects

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

This medicine helps most people but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you experience some of the side effects.

Do not be alarmed by the following lists of possible side effects.

You may not experience any of them.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dry mouth or dry throat
- constipation
- nausea (feeling sick)
- indigestion
- abdominal or stomach pain
- blurred vision
- dry skin

- dry eyes
- dry nasal passages
- confusion
- tiredness
- drowsiness
- abnormal or impaired sense of taste
- decreased appetite

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- a burning sensation in the chest rising up to the throat, also known as heartburn
- changes in electrical activity of the heart (ECG), irregular heartbeat (Torsade de Points)
- pain on urination, urge to urinate, frequent urination or blood in the urine. These can be signs of a urinary tract infection or an inflamed bladder (cystitis).
- sudden signs of allergic reactions such as rash, itching or hives, shortness of breath, wheezing, coughing, or swelling of limbs, face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing

The above list includes serious side effects which may require medical attention. Serious side effects are uncommon or rare.

If you notice any of the following, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the feet or legs
- difficulty in passing urine or unable to pass urine

The above list includes very serious side effects, which may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Vesicare

Storage

Keep your tablets in the blister pack until it is time to take your next dose.

If you take Vesicare out of the packaging it may not keep well.

Keep your Vesicare 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 it on a window sill or in the car.

Heat and dampness can affect some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

There are two strengths of Vesicare tablets:

- Vesicare 5mg tablets are round, light yellow and marked with a triangular logo and “150”.
- Vesicare 10mg tablets are round, light pink and marked with a triangular logo and “151”.

Ingredients

The amount of the active ingredient, solifenacin succinate, in each tablet is:

- Vesicare 5mg – each tablet contains 5mg solifenacin succinate.
- Vesicare 10mg – each tablet contains 10mg solifenacin succinate.

The tablets also contain:

- maize starch
- lactose monohydrate
- hypromellose
- magnesium stearate
- macrogol 8000
- talc
- titanium dioxide
- yellow ferric oxide (Vesicare 5 mg tablets only)
- red ferric oxide (Vesicare 10 mg tablets only)

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Distributor

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This leaflet was prepared in June 2011.

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