

NEW ZEALAND CONSUMER MEDICINE INFORMATION

SOLIFENACIN MYLAN

solifenacin succinate, 5 mg and 10 mg, film coated tablet



What is in this leaflet

This leaflet answers some common questions about Solifenacin Mylan.

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 taking Solifenacin Mylan against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Solifenacin Mylan is used for

Solifenacin Mylan is used to treat 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.

Solifenacin Mylan contains the active ingredient solifenacin succinate. It 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 reason.

This medicine is not addictive.

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

Before you take Solifenacin Mylan

When you must not take it

Do not take Solifenacin Mylan if you have an allergy to:

- any medicine containing solifenacin succinate.
- any of the ingredients listed at the end of this leaflet.
- Some of the 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 give this medicine to children.

Safety and effectiveness in children have not been established.

Do not take Solifenacin Mylan 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 Solifenacin Mylan from the body (see Taking Other Medicines)

Do not take 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:

- 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 breast-feeding.

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 Solifenacin Mylan.

Taking other medicines

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

Some medicines and Solifenacin Mylan may interfere with each other. These include:

- ketoconazole and itraconazole (medicines used to treat fungal infections).
- ritonavir and nelfinavir (medicines used to treat HIV infection).
- pilocarpine (cholinergic receptor agonists, used in the treatment of glaucoma).
- metoclopramide and cisapride (medicines which make the digestive system work faster).
- other anticholinergic medicines, which are medicines used to prevent travel sickness, relieve stomach cramps, treat overactive bladder or Parkinson's Disease.

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

How to take Solifenacin Mylan

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 5 mg or one 10 mg 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 Solifenacin Mylan is too strong or too weak.

How to take it

Swallow the tablets whole with a full glass of water.

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 before or after 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.

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 that you missed.

- This may increase the chance of you getting an unwanted side effect.

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 National Poisons Information Centre (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 taken too much Solifenacin Mylan. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking

Things you must do

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

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take Solifenacin Mylan 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 taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Solifenacin Mylan affects you. This medicine may cause blurred vision, drowsiness and tiredness is

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 Solifenacin Mylan.

This medicine helps most people with an overactive bladder, 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 get some of the side effects.

Do not be alarmed by the following lists of 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:

- constipation
- dry mouth or dry throat
- nausea (feeling sick)
- indigestion
- abdominal or stomach pain
- blurred vision/dizziness
- dry skin
- dry eyes
- dry nasal passages
- confusion
- tiredness
- drowsiness
- abnormal or impaired sense of taste
- decreased appetite
- muscular weakness
- headache

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 the rate or rhythm of the heartbeat. These can be fast (tachycardia, palpitation) or irregular heartbeats (Torsade de Pointes, atrial fibrillation).
- 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 that may require medical attention. Serious side effects are rare

If any of the following happen, 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. You may need urgent medical attention or hospitalisation. These side effects are very 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 taking Solifenacin Mylan

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature

stays below 25°C. Protect from light.

Do not store Solifenacin Mylan 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 destroy 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 taking 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

Solifenacin Mylan 5 mg tablets: yellow film-coated, round, biconvex tablet debossed with M on one side of the tablet and SF over 5 on the other side.

Solifenacin Mylan 10 mg tablets: pink film-coated, round, biconvex tablet debossed with M on one side of the tablet and SF over 10 on the other side.

Ingredients

Solifenacin Mylan contains 5 or 10 mg of solifenacin as the active ingredient.

It also contains:

- lactose
- maize starch
- hypromellose
- purified talc
- magnesium stearate
- titanium dioxide
- propylene glycol
- iron oxide yellow (5 & 10 mg)
- iron oxide red (10 mg)

This medicine does not contain gluten.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: 0800 579 811

Date of Information

03 September 2020
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