

SOLIFENACIN MYLAN

solifenacin succinate

CONSUMER MEDICINE INFORMATION

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 benefits and risks. Your doctor has weighed the risks of you taking SOLIFENACIN MYLAN against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What SOLIFENACIN MYLAN is used for

SOLIFENACIN MYLAN 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.

SOLIFENACIN MYLAN 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.

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 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 take SOLIFENACIN MYLAN if you:

- suffer from urinary retention (inability to urinate or empty your bladder completely)
- are undergoing haemodialysis
- have severe kidney disease and are also taking medicines that can decrease the removal of SOLIFENACIN MYLAN from the body (see Taking other medicines)
- have severe liver disease
- have controlled 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 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:

- low potassium levels or a family history of heart rhythm problems. SOLIFENACIN MYLAN 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 of 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
- automatic 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

Do not give SOLIFENACIN MYLAN to children.

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 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 a pharmacy, supermarket or health food shop.

Some medicines and SOLIFENACIN MYLAN may interfere with each other.

Some medicines can slow down the removal of SOLIFENACIN MYLAN 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 MYLAN.

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 this medicine.

How to take SOLIFENACIN MYLAN

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

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

How much to take

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

How to take it

Try and take SOLIFENACIN MYLAN at the same time each day. SOLIFENACIN MYLAN 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 MYLAN tablets, they may not work as well.

How long to take it

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

Continue taking SOLIFENACIN MYLAN for as long as your doctor tells you to.

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 you missed.

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 13 11 26) 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 SOLIFENACIN MYLAN

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 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 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 change 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.

SOLIFENACIN MYLAN can 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.

Side effects

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

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 list of side effects.

You may not experience any of them.

Stop taking SOLIFENACIN MYLAN and tell your doctor as soon as possible if you experience:

- allergic reactions including swelling of the face, lips, throat or tongue, difficulty breathing.

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

- chest pain or tightness
- swelling of the feet or legs
- changes in electrical activity of the heart (ECG), irregular heartbeat (Torsade de Points).

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

- dry mouth
- nausea, vomiting
- indigestion
- heartburn (dyspepsia)
- stomach discomfort
- urinary tract infection, bladder pain
- difficulty passing urine, inability to empty the bladder
- urgent need to urinate
- blurred vision
- inability to empty the bladder
- dry eyes
- tiredness
- muscle weakness
- accumulation of fluid (swelling) in the lower limbs (oedema)
- dizziness
- sore / dry throat
- cough
- headache
- sleepiness
- hallucination
- confusion
- depression
- fast heartbeat
- palpitations
- skin reactions such as rash itching or hives.

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.

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.

After taking SOLIFENACIN MYLAN

Storage

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.

Keep your tablets a cool dry place where the temperature stays below 25°C.

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 comes in two strengths of tablets:

- SOLIFENACIN MYLAN 5 mg tablets are yellow film-coated, round, biconvex tablet debossed with M one side of the tablet and SF over 5 on the other side.
- SOLIFENACIN MYLAN 10 mg tablets 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 MYLAN is
available in bottles containing 30
tablets.

Ingredients

SOLIFENACIN MYLAN 5 mg
tablets contains 5 mg of solifenacin
succinate as the active ingredient.

SOLIFENACIN MYLAN 10 mg
tablets contains 10 mg of solifenacin
succinate as the active ingredient.

It also contains the following inactive
ingredients:

- lactose monohydrate
- maize starch
- hypromellose
- purified talc
- magnesium stearate
- OPADRY complete film coating
system 03H520077 yellow (PI#
109790) for 5 mg tablets
- OPADRY complete film coating
system 03H540078 (PI# 109766)
pink for 10 mg tablets.

SOLIFENACIN MYLAN contains
sugars (as lactose) and traces of
sulfites.

Sponsor

Alphapharm Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

SOLIFENACIN MYLAN 5 mg
tablet bottle: AUST R 268512

SOLIFENACIN MYLAN 10 mg
tablet bottle: AUST R 268515

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