

PHARMACOR SOLIFENACIN Tablets

PHARMACOR SOLIFENACIN 5 mg film-coated tablets

PHARMACOR SOLIFENACIN 10 mg film-coated tablets

Solifenacin succinate

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before you start taking this medicine.

This leaflet answers some common questions about PHARMACOR SOLIFENACIN.

It does not contain all of 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 PHARMACOR SOLIFENACIN against the benefits they expect it will have 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 PHARMACOR SOLIFENACIN is used for

PHARMACOR SOLIFENACIN 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. PHARMACOR SOLIFENACIN 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 PHARMACOR SOLIFENACIN for another reason. Ask your doctor if you have any questions about why PHARMACOR SOLIFENACIN has been prescribed for you. PHARMACOR SOLIFENACIN is available only with a doctor's prescription.

There is no evidence that PHARMACOR SOLIFENACIN is addictive.

Before you take PHARMACOR SOLIFENACIN

When you must not take it

Do NOT take PHARMACOR SOLIFENACIN if you are allergic to medicines containing 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.

Do not take PHARMACOR SOLIFENACIN if you:

- 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 PHARMACOR SOLIFENACIN from the body (see 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 the arms or legs
- have a blocked gastrointestinal tract or other gastro-intestinal disorders such as ulcerative colitis or toxic megacolon.

Do not take PHARMACOR SOLIFENACIN if the expiry date (Exp.) printed on the pack has passed.

Do not take PHARMACOR SOLIFENACIN if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Do not give PHARMACOR SOLIFENACIN to children.

Tell your doctor if you are pregnant. PHARMACOR SOLIFENACIN may affect your developing baby if you take it during pregnancy. Your doctor will decide if you should take it.

Do not take PHARMACOR SOLIFENACIN 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. PHARMACOR SOLIFENACIN 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 PHARMACOR SOLIFENACIN.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a

pharmacy, supermarket or health food shop.

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

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

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 PHARMACOR SOLIFENACIN.

How to take PHARMACOR SOLIFENACIN

How much to take

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

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

How to take PHARMACOR SOLIFENACIN

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

If you forget to take PHARMACOR SOLIFENACIN

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 PHARMACOR SOLIFENACIN for

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

Keep taking PHARMACOR SOLIFENACIN for as long as your doctor recommends.

If you take too much PHARMACOR SOLIFENACIN (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) if you think you or anyone else may have taken too much PHARMACOR SOLIFENACIN. Do this even if there are no signs of discomfort or poisoning.

While you are taking PHARMACOR SOLIFENACIN

Things you must do

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

Tell all the doctors, dentists and pharmacists who are treating you that you are taking PHARMACOR SOLIFENACIN.

If you become pregnant while taking PHARMACOR SOLIFENACIN, tell your doctor.

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

Things you must not do

Do not stop taking PHARMACOR SOLIFENACIN, or lower the dose, without checking with your doctor.

Do not use PHARMACOR SOLIFENACIN to treat any other conditions unless your doctor tells you to.

Do not give PHARMACOR SOLIFENACIN to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how PHARMACOR SOLIFENACIN affects you.

PHARMACOR SOLIFENACIN 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 PHARMACOR SOLIFENACIN.

Like all other medicines, PHARMACOR SOLIFENACIN 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.

Stop taking PHARMACOR SOLIFENACIN 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
- constipation
- 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.

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.

After using PHARMACOR SOLIFENACIN

Storage

Keep PHARMACOR SOLIFENACIN 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.

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

Do not store PHARMACOR SOLIFENACIN or any other medicine in the bathroom or near a sink.

Do not leave PHARMACOR SOLIFENACIN in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

PHARMACOR SOLIFENACIN comes in two strengths of tablets:

- PHARMACOR SOLIFENACIN 5 mg tablets are light yellow round shaped, film coated tablets debossed with "S5" on one side and plain on other side.
- PHARMACOR SOLIFENACIN 10 mg tablets are light pink, round shaped, film coated tablets debossed with "S10" on one side and plain on other side.

Each Alu-Alu Dessicant Blister Pack contains 10 or 30 tablets.

Each HDPE bottle pack with desiccant contains 30 tablets and 90 tablets for dispensing use only; not for individual patient supply.

Ingredients

The active ingredient in PHARMACOR SOLIFENACIN is solifenacin succinate

- each PHARMACOR SOLIFENACIN tablet contains 5 mg solifenacin succinate; corresponding to 3.8 mg Solifenacin.
- each PHARMACOR SOLIFENACIN tablet contains 10 mg solifenacin succinate; corresponding to 7.5 mg Solifenacin.

The tablets also contain:

- Lactose monohydrate
- Maize starch
- Hypromellose
- Magnesium stearate
- Talc
- Macrogol
- Titanium dioxide
- Iron oxide yellow (5 mg tablets only)
- Iron oxide red (10 mg tablets only)

Supplier

Pharmacor Pty Ltd.
Suite 803, Level 8, Tower A,
The Zenith, 821 Pacific
Highway,
Chatswood, NSW 2067,
Australia

Australian Registration Numbers

PHARMACOR SOLIFENACIN 5 mg Tablet
blister pack - 288255

PHARMACOR SOLIFENACIN 5 mg Tablet
bottle pack - 288261

PHARMACOR SOLIFENACIN 10 mg
Tablet
blister pack - 288262

PHARMACOR SOLIFENACIN 10 mg
Tablet
bottle pack - 288258

AKM SOLIFENACIN 5 mg
Tablet blister pack - 288257

AKM SOLIFENACIN 5 mg
Tablet bottle pack - 288260

AKM SOLIFENACIN 10 mg
Tablet blister pack - 288259

AKM SOLIFENACIN 10 mg
Tablet bottle pack - 288256
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