

SOLIFEN FILM COATED TABLETS 5MG

Solifenacin Succinate (5mg)

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What *Solifen* is used for

Solifen 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.

How *Solifen* works

Solifen 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.

Before you use *Solifen*

- When you must not use it

- If you have an inability to pass water or to empty your bladder completely (urinary retention)
- If you have a severe stomach or bowel condition (including toxic megacolon, a complication associated with ulcerative colitis)
- If you suffer from the muscle disease called myasthenia gravis, which can cause an extreme weakness of certain muscles
- If you suffer from increased pressure in the eyes, with gradual loss of eye sight (glaucoma)
- If you are allergic to solifenacin or any of the other ingredients of this medicine
- If you are undergoing kidney dialysis
- If you have severe liver disease

- If you suffer from severe kidney disease or moderate liver disease AND at the same time are being treated with medicines that may decrease the removal of Solifen from the body (for example, ketoconazole). Your doctor or pharmacist will have informed you if this is the case.

Inform your doctor if you have or ever had any of the above mentioned conditions before treatment with Solifen starts.

Pregnancy and lactation

You should not use Solifen if you are pregnant unless clearly necessary.

Do not use Solifen if you are breast-feeding as solifenacin may get into your breast milk.

Ask your doctor or pharmacist for advice before taking this medicine.

- Before you start to use it

Talk to your doctor or pharmacist before taking Solifen

- If you have trouble emptying your bladder (bladder obstruction) or have difficulty in passing urine (e.g. a thin urine flow). Risk of accumulation of urine in the bladder (urinary retention) is much higher.
- If you have some obstruction of the digestive system (constipation).
- If you are at risk of your digestive system slowing down (stomach and bowel movements). Your doctor will have informed you if this is the case.
- If you suffer from severe kidney disease.
- If you have moderate liver disease.
- If you have a stomach tear (hiatus hernia) or heartburn.
- If you have a nervous disorder (autonomic neuropathy).

- 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.

It is especially important to inform your doctor if you are taking:

- Other anticholinergic medicines, effects and side effects of both medications can be enhanced.
- Cholinergics as they can reduce the effect of Solifen.
- Medicines, like metoclopramide and cisapride, which make the digestive system work faster. Solifen can reduce their effect.
- Medicines, like ketoconazole, ritonavir, nelfinavir, intraconazole, verapamil and diltiazem, which decrease the rate at which Solifen is broken down by the body.
- Medicines like rifampicin, phenytoin and carbamazepine, as they may increase the rate at which Solifen is broken down by the body.
- Medicines such as bisphosphonates that can cause or exacerbate inflammation of the gullet (oesophagitis).

How to use *Solifen*

- How much to use

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

You should swallow the whole tablet with some liquid. It can be taken with or without food, according to your preference. Do not crush the tablets. The usual dose is 5 mg per day, unless your doctor told you to take 10 mg per day.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it
Continue taking *Solifen* for as long as your doctor recommends.

- If you forget to use it
If you forget to take a dose at the usual time, take it as soon as you remember, unless it is time to take your next dose. Never take more than one dose per day. If you are in doubt, always consult your doctor or pharmacist.

- If you use too much (overdose)
Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause: headache, dry mouth, dizziness, drowsiness and blurred vision, perceiving things that are not there (hallucinations), over-excitability, seizures (convulsions), difficulty breathing, elevated heart rate (tachycardia), accumulation of urine in the bladder (urinary retention) and dilated pupils (mydriasis).

While you are using it

- Things you must do
Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Solifen*.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do
Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Solifen* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of
Driving and using machines

Solifen may cause blurred vision and sometimes sleepiness or tiredness. If you suffer from any of these side effects, do not drive or operate machinery.

Solifen contains lactose

If you have been told by your doctor that you have a rare hereditary problem of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption you should not use this medicine

Side effects

Like all medicines, *Solifen* can cause side effects, although not everybody gets them.

Solifen may cause the following side effects:

Very common

- Dry mouth

Common

- Constipation, nausea, indigestion, stomach pain, blurred vision.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of *Solifen*

- Storage
Keep out of the reach and sight of children.

Do not store above 30 °C.

- Disposal
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of

medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Solifen Tablets 5mg
White, oblong, biconvex shaped, film coated tablet plain on both sides.

- Ingredients

Active Ingredient:
Solifenacin succinate

In-active Ingredients:

Pharmatose DCL 11 (Lactose monohydrate), Avicel PH-102 (Microcrystalline Cellulose), Pregelatinized Starch, Magnesium Stearate.

Film-coating Material:
Opadry White YS-1-7027

- MAL number(s):
MAL23036012AZ

Manufacturer

Getz Pharma (Pvt.) Limited,
29-30/27, Korangi Industrial Area,
Karachi - 74900, Pakistan

Product Registration Holder

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Date of revision

09/04/2025

Serial number

NPRA (R2) 21/187