

Solfin 5

Solifenacin Succinate film coated Tablets 5mg

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1. WHAT Solfin 5 IS USED FOR:

Solfin 5 is used to treat the symptoms of a condition called overactive bladder. These symptoms include: having a strong, sudden urge to urinate without prior warning, having to urinate frequently or wetting yourself because you could not get to the bathroom in time.

2. HOW Solfin 5 WORKS:

The active substance of Solfin 5 belongs to the group of anticholinergics. These medicines are used to reduce the activity of an overactive bladder. This enables you to wait longer before having to go to the bathroom and increases the amount of urine that can be held by your bladder.

3. BEFORE YOU USE Solfin 5

- When you must not use it

- Do not take Solfin 5
- 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 Solifenacin Succinate 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 Solfin 5 starts.

Solfin 5 is not to be used in children or adolescents under 18 years.

You should not use Solfin 5 if you are pregnant unless clearly necessary.

Do not use Solfin 5 if you are breast-feeding as solifenacin may get into your breast milk. Ask your doctor or pharmacist for advice before taking this medicine.

Solfin 5 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.

Before you start to use it

Talk to your doctor or pharmacist before taking Solfin 5

- Other anticholinergic medicines, effects and side effects of both medications can be enhanced.
- Cholinergic as they can reduce the effect of Solfin 5.
- Medicines, like metoclopramide and cisapride, which make the digestive system work faster. Solfin 5 can reduce their effect.
- medicines, like ketoconazole, ritonavir, nelfinavir, itraconazole, verapamil and diltiazem, which decrease the rate at which Solfin 5 is broken down by the body
- Medicines like rifampicin, phenytoin and carbamazepine, as they may increase the rate at which Solfin 5 is broken down by the body.
- Medicines such as bisphosphonates that can cause or exacerbate inflammation of the gullet (oesophagitis).

4. HOW TO USE Solfin 5

- How much to use

The usual dose is 5 mg per day, unless your doctor told you to take 10 mg per day.

- When to use it:

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.

- How long to use it:

Take the medicine as long as your doctor tells you to take.

- If you forget to use Solfin 5:

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 Solfin 5 too much (Overdose):

If you have taken too much Solfin 5 or if a child has accidentally taken Solifenacin Succinate Tablets 5mg, contact your doctor or pharmacist immediately.

Symptoms of overdose may include: 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).

5. WHILE YOU ARE USING Solfin 5:

- Things you must do

- Solfin 5 should be taken as directed by your health care provider.
- Talk about any other medicines that you are taking or plan to take. Include those you can get without a prescription.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not take Solfin 5 if you are hypersensitive (allergic) to Solfin 5 or any of its ingredients.
- Do not give Solfin 5 to anyone else, even if they have the same symptoms or condition as you.

Solfin 5

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- Things to be careful of:

Driving and using machines

Solfin 5 may cause blurred vision and sometimes sleepiness or tiredness. If you suffer from any of these side effects, do not drive or operate machinery.

6. SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience an allergic attack, or a severe skin reaction (e.g. blistering and peeling of the skin), you must inform your doctor or pharmacist immediately.

Angioedema (skin allergy that results in the swelling that occurs in the tissue just below the surface of the skin) with airway obstruction (difficulty in breathing) has been reported in some patients on solifenacin succinate. If angioedema occurs, solifenacin succinate should be discontinued immediately and appropriate therapy and/or measures should be taken.

Solfin 5 may cause the following other side effects:

Very common (may affect more than 1 in 10 people)

- dry mouth

Common (may affect up to 1 in 10 people)

- blurred vision
- constipation, nausea, indigestion with symptoms such as abdominal fullness, abdominal pain, burping, nausea, and heartburn (dyspepsia), stomach discomfort

Uncommon (may affect up to 1 in 100 people)

- urinary tract infection, bladder infection
- sleepiness, impaired sense of taste (dysgeusia)
- dry (irritated) eyes
- dry nasal passages
- reflux disease (gastro-oesophageal reflux), dry throat
- dry skin
- difficulty in passing urine
- tiredness, accumulation of fluid in the lower legs (oedema)

Rare (may affect up to 1 in 1,000 people)

- lodging of a large amount of hardened stool in the large intestine (faecal impaction)
- build-up of urine in the bladder due to inability to empty the bladder (urinary retention)
- dizziness, headache
- vomiting
- itching, rash

Very rare (may affect up to 1 in 10,000 people)

- hallucinations, confusion
- allergic rash

Not known (frequency cannot be estimated from the available data)

- decreased appetite, high levels of blood potassium which can cause abnormal heart rhythm
- increased pressure in the eyes
- changes in the electrical activity of the heart (ECG), irregular heartbeat, feeling your heartbeat, faster heart beat
- voice disorder
- liver disorder
- muscle weakness
- renal disorder

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumer → Reporting → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI)).

7. STORAGE AND DISPOSAL OF Solfin 5:

- Storage

Keep this medicine out of the sight and reach of children.

There are no special precautions for storage. Store Solfin 5 below 30°C.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

8. PRODUCT DESCRIPTION

- What it looks like and contents of the pack

Solfin 5 are light yellow colored, round, biconvex, film coated tablets debossed with "L 22" on one side and plain on other side.

Solfin 5 are supplied in blister packs of 10 tablets.

- What Solfin 5 Tablets contains

The active substance is solifenacin succinate 5 mg

The other ingredients are core tablet: Lactose Monohydrate, Pregelatinized Starch, Magnesium Stearate, Purified water

Film coating:

HPMC 2910/Hypromellose 6 cP, Titanium dioxide, Lactose Monohydrate, Polyethylene Glycol 8000, Talc & Iron oxide Yellow

- MAL Number:

MALXXXXXXXXXX

9. MANUFACTURER AND PRODUCT REGISTRATION HOLDER

Manufacturer:

MACLEODS PHARMACEUTICALS LIMITED,

Block N-2, Village Theda, Post Office Lodhimajra, Tehsil Baddi, District Solan, Himachal Pradesh-174101, India.

Product Registration Holder:

MACLEODS PHARMACEUTICAL SDN. BHD.,

A2-27-1 Soho Suites KLCC, Jalan Perak, 50450 Kuala Lumpur, Malaysia.

10. Date of revision

23/02/2026

11. Serial Number

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