

SOFCARE 5mg/10mg Tablet

Solifenacin succinate (5 mg and 10 mg)

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What Sofcare is used for

Sofcare 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.

How Sofcare works

The active substance of Sofcare belongs to the group of anticholinergics which is Solifenacin succinate. 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.

Before you use Sofcare

- When you must not use it

Do not take Sofcare:

- 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 Sofcare 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 Sofcare starts.

Pregnancy and breastfeeding

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

Do not use Sofcare if you are breastfeeding 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 Sofcare

- 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).

Children and adolescents

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

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

Before starting Sofcare, your doctor will assess whether there are other causes for your need to pass urine frequently (for example heart failure (insufficient pumping power of the heart) or kidney disease). If you have a urinary tract infection, your doctor will prescribe you

an antibiotic (a treatment against particular bacterial infections).

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken or might take other medicines.

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 Sofcare.
- Metoclopramide and Cisapride which make the digestive system work faster. Sofcare can reduce their effect.
- Ketoconazole, Ritonavir, Nelfinavir, Itraconazole, Verapamil and Diltiazem, which decrease the rate at which Sofcare is broken down by the body.
- Rifampicin, Phenytoin and Carbamazepine, as they may increase the rate at which Sofcare is broken down by the body.
- Biphosphonates, that can cause or exacerbate inflammation of the gullet (esophagitis).

How to use Sofcare

- How much to use

Adults, including the elderly

The recommended dose is 5 mg Solifenacin succinate once daily. If needed, the dose may be increased to 10 mg Solifenacin succinate once daily.

Pediatric population

The safety and efficacy of Solifenacin succinate in children have not yet been established. Therefore, Solifenacin succinate should not be used in children.

Patients with renal impairment

No dose adjustment is necessary for patients with mild to moderate renal impairment (creatinine clearance > 30 mL/min). Patients with severe renal impairment (creatinine clearance ≤ 30 mL/min) should be treated with caution and receive not more than 5 mg once daily.

Patients with hepatic impairment

No dose adjustment is necessary for patients with mild hepatic

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impairment. Patients with moderate hepatic impairment (Child-Pugh score of 7 to 9) should be treated with caution and receive no more than 5 mg once daily.

Potent inhibitors of cytochrome P450 3A4

The maximum dose of Solifenacin succinate should be limited to 5 mg when treated simultaneously with Ketoconazole or therapeutic doses of other potent CYP3A4-inhibitors e.g. Ritonavir, Nelfinavir and Itraconazole.

- When to use it

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.

- How long to use it

If you stop taking Sofcare, your symptoms of overactive bladder may return or worsen. Always consult your doctor if you are considering stopping the treatment.

- 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)

If you have taken too much Sofcare or if a child has accidentally taken Sofcare, 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, difficulty breathing, elevated heart rate, accumulation of urine in the bladder and dilated pupils.

While you are using it

- Things you must do

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

- Things you must not do

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- Things to be careful of

Driving and using machines

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

Sofcare 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, this medicine can cause side effects, although not everybody gets them.

Due to the pharmacological effect of Solifenacin, Sofcare may cause anticholinergic undesirable effects of (in general) mild or moderate severity. The frequency of anticholinergics undesirable effects is dose related.

Very common side effect:

- Dry mouth

Common side effect:

- Blurred vision
- Constipation
- Nausea
- Indigestion
- Abdominal pain
- life-threatening allergic reaction
- Decreased appetite
- Hallucinations, confusion, rash
- Dizziness
- Headache
- Eye disorder
- changes in the electrical activity of the heart (ECG), irregular heartbeat, feeling your heartbeat, faster heartbeat, voice disorder
- Vomiting
- indigestion with symptoms such as abdominal fullness, abdominal pain, burping, nausea, and heartburn
- Liver disorder and liver function test abnormal

- Red and itchy skin, hives
- accumulation of fluid in the lower legs
- Muscle weakness
- Renal impairment

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

Storage and Disposal of Sofcare

-Storage

Keep medicines out of reach of children.

Store at temperature of not more than 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 you protect the environment.

Product Description

- What it looks like?

5 mg: Light yellow, round, biconvex, film coated tablet with engraved 5 on one side and plain on the other side

10 mg: Light pink, oblong, biconvex, film coated tablet with engraved 10 on one side and plain on the other side

- Ingredients

- Active ingredient:

Solifenacin succinate

- Inactive ingredients:

Calcium phosphate dihydrate powder, Lactose monohydrate, Pregelatinized starch (National 78-1551), Edetate disodium, Sodium metabisulfite, Povidone (PVP K-30), Butylated hydroxytoluene, Isopropyl alcohol, Purified water, Croscarmellose sodium, Colloidal silicon dioxide (Aerosil 200), Magnesium stearate, Hypromellose (HPMC 2910), Propylene glycol, Methylene chloride, Kollicoat IR [Combination of Polyvinyl alcohol units (75%), Polyethylene glycol units (25%) and Colloidal

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anhydrous silica (Approx 0.3%),
Titanium dioxide, Talc, *Iron
oxide yellow (C.I. No. 77492),
Iron oxide red (C.I. No. 77491),
Polyethylene glycol (PEG 6000)
and Acetone

- *MAL Number:* -
MAL21126004AZ

Manufacturer

UNISON LABORATORIES CO., LTD.
39 Moo 4, Klong Udomcholjorn, Muang
Chachoengsao, Chachoengsao 24000
Thailand.

Product Registration Holder

Medispec (M) Sdn Bhd
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