

RENAXIN FILM COATED TABLETS

Solifenacin Succinate 5mg, 10mg

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What Renaxin is used for

Renaxin 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 Renaxin works

Renaxin contains an active ingredient, Solifenacin Succinate which belongs to the group of anticholinergics. These medicines are used to reduce the activity of an overactive bladder. By relaxing the muscles in the bladder, it improves your ability to control your urination. 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 Renaxin

- When you must not use it

Do not take Renaxin:

- if you are allergic to active substance or any of the other ingredients of this medicine,
- 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 an acute form of colonic distension (toxic megacolon); a complication associated with an inflammatory bowel disease that causes long lasting inflammation and ulcers (sores) in your digestive tract (ulcerative colitis),
- if you suffer from the muscle disease, which can cause an extreme weakness of certain

muscles (myasthenia gravis),

- if you suffer from increased pressure in the eyes, with gradual loss of eye sight (glaucoma),
- 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 from the body (for example, ketoconazole – antifungal drug). 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 Renaxin starts.

- *Before you start to use it*

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not use Renaxin if you are pregnant unless clearly necessary. Do not use Renaxin if you are breast-feeding as solifenacin may get into your breast milk.

- *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 Renaxin.
- Metoclopramide and Cisapride which make the digestive system work faster. Renaxin can reduce their effect.
- Ketoconazole, Ritonavir, Nelfinavir, Itraconazole, Verapamil and Diltiazem, which decrease the rate at which Renaxin is broken down by the body.
- Rifampicin, Phenytoin and Carbamazepine, as they may increase the rate at which Renaxin is broken down by the body.

- Biphosphonates, that can cause or exacerbate inflammation of the gullet (esophagitis).

How to use Renaxin

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

You should swallow the whole tablet with some liquid. Do not crush the tablets.

- When to use it

Use as directed by your doctor or pharmacist. Renaxin can be taken with or without food.

- How long to use it

Continue taking Renaxin for as long as your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

If you have taken too much Renaxin or if a child has accidentally taken Renaxin, 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.

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– 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:

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

Renaxin 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 any other medicines, Renaxin may cause side effects although not everyone may get it.

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.

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

Renaxin may cause the following other side effects:

- dry mouth,
- blurred vision,
- constipation, nausea, indigestion with symptoms such as abdominal fullness, abdominal pain, burping, heartburn (dyspepsia), stomach discomfort.
- urinary tract infection, bladder infection,
- build-up of urine in the bladder due to inability to empty the bladder (urinary retention),
- hallucinations, confusion,
- allergic rash.

- 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 (Torsade de Pointes), being able to feel your heartbeat, faster heartbeat,
- muscle weakness,
- renal disorder.

Visit your doctor or pharmacist immediately if you experience any side effects listed or not listed above 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 npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Renaxin

– Storage

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister strip after EXP. The expiry date refers to the last day of that month.

Store below 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

Renaxin 5mg Film Coated Tablets

Light yellow, round shaped film coated tablets debossed with “N” on one side and “25” other side.

Renaxin 10mg Film Coated Tablets

Light pink, round shaped film coated

tablets debossed with “N” on one side and “24” other side.

Renaxin 5mg Film Coated Tablets

The tablets are available in 1 x 10's, 3 x 10's, 6 x 10's, 10 x 10's, 50 x 10's, 100 x 10's, 1 x 14's, 2 x 14's, 4 x 14's, 6 x 14's, 8 x 14's, 12 x 14's in blister form packed in the outer carton.

Renaxin 10mg Film Coated Tablets

The tablets are available in 1 x 10's, 3 x 10's, 6 x 10's, 10 x 10's, 50 x 10's, 100 x 10's, 1 x 14's, 2 x 14's, 4 x 14's, 6 x 14's, 8 x 14's, 12 x 14's in blister form packed in the outer carton.

– Ingredients

– Active ingredient(s)

The active substance is Solifenacin Succinate. One tablet contains Solifenacin Succinate 5mg and 10mg.

– Inactive ingredient

- Tablet core
 - Lactose Monohydrate
 - Corn Starch
 - Hypromellose
 - Magnesium Stearate

Film coat

- Opadry Complete Film Coating System 03F12967 Yellow (5mg)
Component: Hypromellose, Talc, Macrogol, Titanium Dioxide, Iron Oxide Yellow
- Opadry Complete Film Coating System 03F14895 Pink (10mg),
Component: Hypromellose, Talc, Macrogol, Titanium Dioxide, Iron Oxide Red

– MAL numbers

- Renaxin 5mg Film Coated Tablets: MAL22096036AZ
- Renaxin 10mg Film Coated Tablets: MAL22096037AZ

Manufacturers

Novugen Pharma Sdn.Bhd.
No. 27, Jalan Lengku Teknologi 2,
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Product Registration Holder

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19/07/2024

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