

QUEMED 5 MG TABLETS

QUEMED 10 MG TABLETS

Solifenacin succinate (5mg / 10mg)

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What Quemed is used for

Quemed 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 Quemed works

The active substance of Quemed 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 Quemed

– When you must not use it

Do not take Quemed

- 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 Quemed 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 Quemed if you are pregnant unless clearly necessary.

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

– Taking other medicines

Tell your doctor if you are taking, have recently taken or might take any other medicines.

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

- other anticholinergic medicines (drugs that block the action of the neurotransmitter acetylcholine), effects and side effects of both medications can be enhanced,
- cholinergics (drugs that mimic the action of acetylcholine) as they can reduce the effect of solifenacin,
- medicines, like metoclopramide (drug that treats and prevents nausea and vomiting) and cisapride (drug that increases motility in the upper gastrointestinal tract), They make the digestive system work faster - solifenacin can reduce their effect,
- medicines, like ketoconazole or itraconazole (antifungal drugs), ritonavir or nelfinavir (drugs that treat HIV/AIDS), verapamil or diltiazem (drugs that treat hypertension and other conditions related to heart disease), which decrease the rate at which solifenacin is broken down by the body,
- medicines like rifampicin (antibiotic drug), phenytoin and carbamazepine (anti-epileptic drugs), as they may increase the rate at which solifenacin is broken down by the body,
- medicines such as bisphosphonates (drugs that prevent the loss of bone density), that can cause or exacerbate inflammation of the gullet (oesophagitis).

How to use Quemed

– 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

It can be taken with or without food, according to your preference.

– How long to use it

You are advised to take this product as long as your doctor tells you to.

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 Quemed or if a child has accidentally taken Quemed, 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).

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

Talk to your doctor or pharmacist before taking Quemed

- 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).

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

Before starting Quemed, 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).

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.

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, Quemed should be discontinued immediately and appropriate therapy and/or measures should be taken.

Quemed 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.

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 Quemed

– Storage

Store below 30°C and in original packaging.

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

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

– 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 protect the environment.

Product Description

– What it looks like

Film-coated tablet.

Quemed 5 mg: yellow round biconvex film-coated tablets, plain on both sides, diameter 6 mm, without break line.

Quemed 10 mg: pink round biconvex film-coated tablets, plain on both sides, diameter 7 mm, without break line.

– Ingredients

– Active Ingredient:
Solifenacin succinate

– Inactive Ingredients:
Lactose monohydrate, Maize starch, Talc, Magnesium stearate

Quemed 5 mg: Opadry yellow OY 32823 (Hypromellose 6cP, Titanium dioxide, Macrogol 400, Ferric oxide Yellow, Ferric oxide Red)

Quemed 10 mg: Opadry white 03B28796 (Hypromellose 6cP, Titanium dioxide, Macrogol 400), Opadry brown 02F23883 (Hypromellose 5cP, Titanium dioxide, Macrogol 6000, Ferric oxide Yellow, Ferric oxide Red)

– MAL number

Quemed 5mg: MAL21066018AZ

Quemed 10mg: MAL21066019AZ

Manufacturer

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Product Registration Holder

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