

Package leaflet: Information for the user

Solifenacin Clonmel 5mg Film-coated Tablets
Solifenacin Clonmel 10mg Film-coated Tablets

Solifenacin succinate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Solifenacin Clonmel is and what it is used for
2. What you need to know before you take Solifenacin Clonmel
3. How to take Solifenacin Clonmel
4. Possible side effects
5. How to store Solifenacin Clonmel
6. Contents of the pack and other information

1. What Solifenacin Clonmel is and what it is used for

The active substance of Solifenacin Clonmel belongs to the group called 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.

Solifenacin Clonmel 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. What you need to know before you take Solifenacin Clonmel

DO NOT take Solifenacin Clonmel

- if you are unable 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 (listed in section 6)
- 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 Clonmel 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 have ever had any of the above mentioned conditions before treatment with this medicine starts

Warnings and precautions

Talk to your doctor or pharmacist before taking Solifenacin Clonmel

- 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 disorder of the nervous system called autonomic neuropathy

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

Before starting Solifenacin Clonmel, 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).

Children and adolescents

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

Other medicines and Solifenacin Clonmel

Tell your doctor or pharmacist 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, as the effects and side effects of both medications could be increased. Please ask your doctor if your medicine belongs to this group
- cholinergics, as they can reduce the effect of Solifenacin Clonmel. Please ask your doctor if your medicine belongs to this group
- medicines, like metoclopramide and cisapride, which make the digestive system work faster. Solifenacin Clonmel can reduce their effect
- medicines, like ketoconazole, itraconazole (medicines used to treat fungal infections), ritonavir, nelfinavir (medicines used to treat HIV infections) and verapamil, diltiazem (medicines used to treat high blood pressure and heart diseases). These medicines decrease the rate at which Solifenacin Clonmel is broken down by the body
- medicines like rifampicin (medicine used to treat tuberculosis and other bacterial infections) and phenytoin, carbamazepine (medicines used to treat epilepsy). They may increase the rate at which Solifenacin Clonmel is broken down by the body
- medicines such as bisphosphonates, that can cause or exacerbate inflammation of the gullet (oesophagitis). Please ask your doctor if your medicine belongs to this group

Solifenacin Clonmel with food and drink

This medicine can be taken with or without food, depending on your preference.

Pregnancy and breast-feeding

You should not use Solifenacin Clonmel if you are pregnant unless your doctor thinks it is necessary. Do not use this medicine if you are breast-feeding as solifenacin may pass into your breast milk.

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

Driving and using machines

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

Solifenacin Clonmel contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Solifenacin Clonmel

Instructions for proper use

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

Dosage

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

Method of administration

You should swallow the tablet whole with some liquid, e.g. a glass of water. It can be taken with or without food, according to your preference. Do not crush the tablets.

Use in children and adolescents

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

If you take more Solifenacin Clonmel than you should

If you have taken too much Solifenacin Clonmel or if a child has accidentally taken this medicine, 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).

If you forget to take Solifenacin Clonmel

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. Do not take a double dose to make up for a forgotten dose. If you are in doubt, always consult your doctor or pharmacist.

If you stop taking Solifenacin Clonmel

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking Solifenacin Clonmel and seek medical help immediately if you notice any of the following side effects

- allergic attack, or a severe skin reaction (e.g. blistering and peeling of the skin)
- 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.

Solifenacin Clonmel 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
- acid reflux (gastrooesophageal 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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Solifenacin Clonmel

This medicinal product does not require any special temperature storage conditions. Store in original package in order to protect from humidity.

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 EXP. The expiry date refers to the last day of that month.

Do not use this medicine if the pack is damaged or shows signs of tampering.

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.

6. Contents of the pack and other information

What Solifenacin Clonmel contains

The active substance is solifenacin succinate.

Each film-coated tablet contains 5 mg solifenacin succinate equivalent to 3.8 mg solifenacin.

Each film-coated tablet contains 10 mg solifenacin succinate equivalent to 7.5 mg solifenacin.

The other ingredients are

Tablet core

Lactose monohydrate, Maize starch, Hypromellose, Magnesium stearate.

Film-coating

Hypromellose, Titanium Dioxide (E171), Macrogol 8000, Talc and Iron Oxide Yellow (E172) (5 mg tablet), Iron Oxide Red (E172) (10 mg tablet).

What Solifenacin Clonmel looks like and contents of the pack

Solifenacin Clonmel 5 mg film-coated tablets are round, light yellow, biconvex film-coated tablets.

Solifenacin Clonmel 10 mg film-coated tablets are round, light pink, biconvex film-coated tablets.

Solifenacin Clonmel 5 mg, 10 mg film-coated tablets are supplied in blister packs of 10, 20, 30, 40, 50, 60, 80, 90, 100, 105, 120, 150, 180 and 200 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel, Germany

Centrafarm Services B.V., Van de Reijtstraat 31-E, 4814 NE Breda, The Netherlands

STADA Arzneimittel GmbH, Muthgasse 36/2, 1190 Wien, Austria

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

STADA M&D SRL, Str. Trascăului, nr 10, RO-401135, Turda, Romania

IBS-Experts International, d.o.o., Ruševje 15, 10290 Zaprešić, Republic of Croatia

This medicinal product is authorised in the Member States of the EEA under the following names:

NL: Solifenacinesuccinaat CF 5 mg, 10 mg, filmomhulde tabletten
AT: Solifenacin STADA 5 mg, 10 mg Filmtabletten
BE: Solifenacine EG 5 mg, 10 mg filmomhulde tabletten
DE: Solifenacinsuccinat AL 5 mg, 10 mg Filmtabletten
DK: Solifenacin STADA 5 mg, 10 mg filmovertrukne tabletter
ES: Solifenacina STADA 5 mg, 10 mg comprimidos recubiertos con película EFG
FI: Solifenacin STADA 5 mg, 10 mg kalvopäällysteinen tabletti
FR: SOLIFENACINE EG 5 mg, 10 mg, comprimé pelliculé
HR: Solifenacin STADA 5 mg, 10 mg, filmom obložene tablete
HU: Urofenacin 5 mg, 10 mg filmtabletta
IE: Solifenacin Clonmel 5 mg, 10 mg film-coated tablets
LU: Solifenacine EG 5 mg, 10 mg comprimé pelliculé
RO: VESISTAD 5 mg, 10 mg comprimate filmate
SE: Solifenacin STADA 5 mg, 10 mg filmdragerad tablett
SK: Solifenacin STADA 5 mg, 10 mg
UK: Solifenacin 5 mg, 10 mg film-coated tablets

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