**Package leaflet: Information for the user**

**Solifenacin/Tamsulosin Clonmel 6 mg/0.4 mg modified-release tablets**

solifenacin succinate/tamsulosin hydrochloride

**Read all of this leaflet carefully before you start using 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/Tamsulosin Clonmel is and what it is used for

Solifenacin/Tamsulosin Clonmel is a combination of two different medicines called solifenacin and tamsulosin in one tablet. Solifenacin belongs to a group of medicines called anticholinergics and tamsulosin belongs to a group of medicines called alpha-blockers.

Solifenacin/Tamsulosin Clonmel is used in men to treat both moderate to severe storage symptoms and voiding symptoms of the lower urinary tract which are caused by bladder problems and an enlarged prostate (benign prostatic hyperplasia). Solifenacin/Tamsulosin Clonmel is used when previous treatment with a monoproduct for this condition did not relieve symptoms adequately.

As the prostate grows, it can lead to urinary problems (voiding symptoms) such as hesitancy (difficulty to start urinating), difficulty urinating (poor stream), dribbling and feeling of incomplete bladder emptying. At the same time, the bladder is also affected and contracts spontaneously at times you do not want to void. This causes storage symptoms such as changes in bladder sensation, urgency (having a strong, sudden desire to urinate without prior warning), and having to urinate more frequently.

Solifenacin reduces the undesired contractions of your bladder and increases the amount of urine that your bladder can hold. Therefore you can wait longer before you have to go to the toilet. Tamsulosin enables urine to pass more readily through the urethra and facilitates urination.

## 2. What you need to know before you use Solifenacin/Tamsulosin Clonmel

**Do not use Solifenacin/Tamsulosin Clonmel if:**
- you are allergic to solifenacin or tamsulosin or any of the other ingredients of this medicine (listed in section 6).
- you are undergoing kidney dialysis.
- you have a severe liver disease.
- you suffer from severe kidney disease AND if, at the same time, you are being treated with medicines that may decrease the removal of Solifenacin/Tamsulosin Clonmel from the body (for example ketoconazole, ritonavir, nelfinavir, itraconazole). Your doctor or pharmacist will have informed you if this is the case.

- you suffer from moderate liver disease AND if, at the same time, you are being treated with medicines that may decrease the removal of Solifenacin/Tamsulosin Clonmel from the body (for example ketoconazole, ritonavir, nelfinavir, itraconazole). Your doctor or pharmacist will have informed you if this is the case.
- you have a severe stomach or bowel condition (including toxic megacolon, a complication associated with ulcerative colitis).
- you suffer from a muscle disease called myasthenia gravis, which can cause an extreme weakness of certain muscles.
- you suffer from increased pressure in the eyes (glaucoma), with gradual loss of eye sight.
- you suffer from fainting due to reduced blood pressure when changing posture (going to sit up or stand up); this is called orthostatic hypotension.

Tell your doctor if you think that any of these conditions apply to you.

**Warnings and precautions**
Talk to your doctor or pharmacist before using Solifenacin/Tamsulosin Clonmel if:
- you have an inability to pass water (urinary retention).
- you have some obstruction of the digestive system.
- 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.
- you have a stomach tear (hiatus hernia) or heartburn and/or if, at the same time, you are taking medicines that can cause or worsen oesophagitis.
- you suffer from a certain type of nervous disease (autonomic neuropathy).
- you suffer from severe kidney disease.
- you suffer from moderate liver disease.

Periodic medical examinations are necessary to monitor the development of the condition you are being treated for.

Solifenacin/Tamsulosin Clonmel can affect your blood pressure which can make you feel dizzy, light headed or rarely can make you faint (orthostatic hypotension). You should sit or lie down if you experience any of these symptoms until they disappear.

If you are undergoing or have been scheduled for eye surgery because of cloudiness of the lens (cataract) or increased pressure in the eyes (glaucoma), please inform your eye specialist that you have previously used, are using or are planning to use Solifenacin succinate/tamsulosin hydrochloride. The specialist can then take appropriate precautions with respect to medication and surgical techniques to be used. Ask your doctor whether or not you should postpone or temporarily stop taking this medicine when undergoing eye surgery because of a cloudy lens (cataract) or increased pressure in the eye (glaucoma).

**Children and adolescents**
Do not give this medicine to children and adolescents.

**Other medicines and Solifenacin/Tamsulosin Clonmel**
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

It is especially important to inform your doctor if you are using:
- medicines like ketoconazole, erythromycin, ritonavir, nelfinavir, itraconazole, verapamil, diltiazem, and paroxetine which decrease the rate at which Solifenacin/Tamsulosin Clonmel is removed from the body.
- other anticholinergic medicines, as effects and side effects of both medications can be enhanced if you are taking two medicines of the same type.
- cholinergics, as they can reduce the effect of Solifenacin/Tamsulosin Clonmel.
- medicines like metoclopramide and cisapride, which make the digestive system work faster. Solifenacin/Tamsulosin Clonmel can reduce their effect.
- other alpha-blockers, as this may cause an unwanted decrease in blood pressure.

- medicines such as bisphosphonates, that can cause or exacerbate inflammation of the gullet (oesophagitis).

**Solifenacin/Tamsulosin Clonmel with food and drink**
Solifenacin/Tamsulosin Clonmel can be taken with or without food, according to your preference.

**Pregnancy, breast-feeding and fertility**
Solifenacin/Tamsulosin Clonmel is not indicated for use by women.

In men, abnormal ejaculation has been reported (ejaculation disorder). This means that the semen does not leave the body via the urethra, but instead goes into the bladder (retrograde ejaculation) or the ejaculation volume is reduced or absent (ejaculation failure). This phenomenon is harmless.

**Driving and using machines**
Solifenacin/Tamsulosin Clonmel might cause dizziness, blurred vision, tiredness and, uncommonly, sleepiness. If you suffer from these side effects, do not drive or operate machinery.

**Solifenacin/Tamsulosin Clonmel contains sodium**
This medicine contains less than 1 mmol sodium (23 mg) per one tablet, that is to say essentially 'sodium-free'.

## 3. How to use Solifenacin/Tamsulosin Clonmel

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

The maximum daily dose is one tablet containing 6 mg of solifenacin and 0.4 mg of tamsulosin, taken by mouth. It can be taken with or without food, according to your preference. Do not crush or chew the tablet.

**If you take more Solifenacin/Tamsulosin Clonmel than you should**
If you have taken more tablets than you have been told to take, or if someone else accidentally takes your tablets, contact your doctor, pharmacist or hospital immediately for advice.

In case of an overdose your doctor may treat you with activated charcoal; emergency stomach washout may be useful if performed within 1 hour of overdose. Do not induce vomiting.

Symptoms of overdose may include: dry mouth, dizziness, and blurred vision, perceiving things that are not there (hallucinations), over-excitability, seizures (convulsions), difficulty breathing, increased heart rate (tachycardia), inability to completely or partially empty the bladder or pass urine (urinary retention) and/or an unwanted decrease in blood pressure.

**If you forget to take Solifenacin/Tamsulosin Clonmel**
Take your next tablet of Solifenacin/Tamsulosin Clonmel as normal. Do not take a double dose to make up for a forgotten tablet.

**If you stop taking Solifenacin/Tamsulosin Clonmel**
If you stop taking Solifenacin/Tamsulosin Clonmel, your original complaints 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.

The most serious side effect that has uncommonly (may affect up to 1 in 100 men) been observed during treatment with Solifenacin succinate/tamsulosin hydrochloride in clinical studies is acute urinary retention,

which is a sudden inability to pass urine. If you think you may have this, see a doctor straight away. You may need to stop taking Solifenacin succinate/tamsulosin hydrochloride.

Allergic reactions could occur with Solifenacin succinate/tamsulosin hydrochloride:
- Uncommon signs of allergic reactions can include skin rash (which can be itchy) or hives (urticaria).
- Rare symptoms include swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema). Angioedema has been reported rarely on tamsulosin and very rarely with solifenacin. If angioedema occurs, Solifenacin/Tamsulosin Clonmel should be stopped immediately and not started again.

If you experience an allergic attack, or a severe skin reaction (e.g. blistering and peeling of the skin), you must inform your doctor immediately, and stop using Solifenacin succinate/tamsulosin hydrochloride. Appropriate therapy and/or measures should be taken.

**Common** side effects (may affect up to 1 in 10 men)
- dizziness
- blurred vision
- dry mouth, indigestion (dyspepsia), constipation, feeling sick (nausea), abdominal pain
- abnormal ejaculation (ejaculation disorder). This means that semen does not leave the body via the urethra, but instead goes into the bladder (retrograde ejaculation) or the ejaculation volume is reduced or absent (ejaculation failure) This phenomenon is harmless.
- tiredness (fatigue)

**Uncommon** side effects (may affect up to 1 in 100 men)
- urinary tract infection, bladder infection (cystitis)
- sleepiness (somnolence), impaired sense of taste (dysgeusia), headache
- dry eyes
- fast or uneven heartbeat (palpitations)
- feeling dizzy or weak especially when you stand up (orthostatic hypotension)
- runny or blocked nose (rhinitis), dry nose
- reflux disease (gastro-oesophageal reflux), diarrhea, dry throat, being sick (vomiting)
- itching (pruritus), dry skin
- difficulty in passing urine
- accumulation of fluid in the lower legs (oedema), tiredness (asthenia)

**Rare** side effects (may affect up to 1 in 1,000 men)
- feeling faint (syncope)
- lodging of a large amount of hardened stool in the large intestine (faecal impaction)
- skin allergy that results in the swelling that occurs in the tissue just below the surface of the skin (angioedema)

**Very rare** side effects (may affect up to 1 in 10,000 men)
- hallucinations, confusion
- rash, inflammation and blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals (Stevens-Johnson syndrome), allergic skin reaction (Erythema multiforme)
- long-lasting and painful erection (usually not during sexual activity) (priapism)

**Not known** side effects (frequency cannot be estimated from the available data)
- serious allergic reaction which causes difficulty in breathing or dizziness (anaphylactic reaction)
- decreased appetite, high levels of blood potassium (hyperkalaemia) which can cause abnormal heart rhythm
- rapid decrease of awareness and general mind functioning (delirium)
- during an operation of the eye for cloudiness of the lens (cataract) or for increased pressure in the eye (glaucoma) the pupil (the black circle in the middle of your eye) may not increase in size as needed. Also,

the iris (the coloured part of the eye) may become floppy during surgery, increased pressure in the eyes (glaucoma), impaired vision
- irregular or unusual heart beat (QT prolongation, Torsade de Pointes, atrial fibrillation, arrhythmia), faster heartbeat (tachycardia)
- shortness of breath (dyspnoea), voice disorder, nose bleeds (epistaxis)
- bowel obstruction (ileus), abdominal discomfort
- liver disorder
- inflammation of the skin causing redness and scaling over large areas of the body (exfoliative dermatitis)
- muscle weakness
- renal disorder

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. 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/Tamsulosin Clonmel

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.

Store below 25 °C.

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/Tamsulosin Clonmel contains**
- The active substances are solifenacin succinate and tamsulosin hydrochloride. Each modified-release tablet contains 6 mg solifenacin succinate and 0.4 mg tamsulosin hydrochloride.
- The other ingredients are calcium hydrogen phosphate, cellulose, microcrystalline (E460), croscarmellose sodium (E468), hypromellose (E464), iron oxide red (E172), magnesium stearate (E470b), macrogol, high-molecular mass, macrogol, silica, colloidal anhydrous, titanium dioxide (E171).

**What Solifenacin/Tamsulosin Clonmel looks like and contents of the pack**
Solifenacin/Tamsulosin Clonmel <6 mg/0.4 mg> <modified-release tablets> are red, round, biconvex, film-coated tablets, debossed with "T7S" on one side.

Solifenacin/Tamsulosin Clonmel are available in blisters containing 10, 14, 20, 28, 30, 50, 56, 60, 90, 100 or 200 modified-release tablets or perforated unit-dose blisters containing 10 x 1, 14 x 1, 20 x 1, 28 x 1, 30 x 1, 50 x 1, 56 x 1, 60 x 1, 90 x 1, 100 x 1 or 200 x 1 modified-release 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:
Synthon Hispania S.L., C/ Castelló, nº1, Sant Boi de Llobregat, 08830 Barcelona, Spain
Synthon BV, Microweg 22, 6545 CM Nijmegen, the Netherlands
Synthon s.r.o., Brněnská 32/čp. 597, 678 01 Blansko, Czech Republic

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

**This medicine is authorised in the Member States of the European Economic Area under the following names:**

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| The Netherlands: | Solifenacinesuccinaat/Tamsulosinehydrochloride CF 6 mg/0,4 mg, tabletten met gereguleerde afgifte |
| Austria: | Solifenacin/Tamsulosin 6 mg/0,4 mg Tabletten mit veränderter Wirkstofffreisetzung |
| Belgium: | Solifenacine/Tamsulosine EG 6 mg/0,4 mg tabletten met gereguleerde afgifte |
| Croatia: | SEVONO 6 mg/0,4 mg tablete s prilagođenim oslobađanjem |
| Czech Republic: | Velisan |
| Denmark: | Solifenacin/Tamsulosin STADA |
| Germany: | Solifenacin/Tamsulosin STADAPHARM 6 mg/0,4 mg Tabletten mit veränderter Wirkstofffreisetzung |
| Finland: | Solifenacin/Tamsulosin STADA |
| Ireland: | Solifenacin succinate/Tamsulosin hydrochloride Clonmel 6 mg/0.4 mg modified-release tablets |
| Luxembourg: | Solifenacine / Tamsulosine EG 6 mg / 0,4 mg comprimés à libération modifiée |
| Norway: | Solifenacin/Tamsulosin STADA |
| Portugal: | Solifenacina + Tansulosina Ciclum |
| Spain: | Solifenacina / Tamsulosina STADAFARMA 6 mg / 0,4 mg comprimidos de liberación modificada EFG |

**This leaflet was last revised in November 2023**.