Package leaflet: Information for the patient

Trusitev SR 2 mg prolonged-release capsules, hard
Trusitev SR 4 mg prolonged-release capsules, hard
tolterodine tartrate

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 Trusitev SR is and what it is used for

The active substance in Trusitev SR is tolterodine. Tolterodine belongs to a class of medicines called antimuscarinics.

Trusitev SR is used for the treatment of the symptoms of overactive bladder syndrome. If you have overactive bladder syndrome, you may find that:
- you are unable to control urination.
- you need to rush to the toilet with no advance warning and/or go to the toilet frequently.

2. What you need to know before you take Trusitev SR

Do not take Trusitev SR
- if you are allergic to tolterodine or any of the other ingredients of this medicine (listed in section 6).
- if you are unable to pass urine from the bladder (urinary retention).
- if you have an uncontrolled narrow-angle glaucoma (high pressure in the eyes with loss of eyesight that is not being adequately treated).
- if you suffer from myasthenia gravis (excessive weakness of the muscles).
- if you suffer from severe ulcerative colitis (ulceration and inflammation of the colon).
- if you suffer from a toxic megacolon (acute dilatation of the colon).

Warnings and precautions
Talk to your doctor or pharmacist before taking Trusitev SR
- if you have difficulties in passing urine and/or a poor stream of urine.
- if you have a gastro-intestinal disease that affects the passage and/or digestion of food.

- if you suffer from kidney problems (renal insufficiency).
- if you have a liver condition.
- if you suffer from neurological disorders that affect your blood pressure, bowel or sexual function (any neuropathy of the autonomic nervous system).
- if you have a hiatus hernia (herniation of an abdominal organ).
- if you ever experience decreased bowel movements or suffer from severe constipation (decreased gastro-intestinal motility).
- if you have a heart condition such as:
  - an abnormal heart tracing (ECG)
  - a slow heart rate (bradycardia)
  - relevant pre-existing cardiac diseases such as: cardiomyopathy (weak heart muscle), myocardial ischaemia (reduced blood flow to the heart), arrhythmia (irregular heartbeat) and heart failure
- if you have abnormally low levels of potassium (hypokalaemia), calcium (hypocalcaemia) or magnesium (hypomagnesaemia) in your blood.

Other medicines and Trusitev SR
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tolterodine, the active substance of Trusitev SR, may interact with other medicines.

It is not recommended to take Trusitev SR in combination with:
- some antibiotics (containing e.g. erythromycin, clarithromycin)
- medicines used for the treatment of fungal infections (containing e.g. ketoconazole, itraconazole)
- medicines used for the treatment of HIV

Trusitev SR should be used with caution when taken in combination with:
- medicines that affect the passage of food (containing e.g. metoclopramide and cisapride)
- medicines for the treatment of irregular heartbeat (containing e.g. amiodarone, sotalol, quinidine, procainamide
- other medicines with a similar mode of action to Trusitev SR (antimuscarinic properties) or medicines with an opposite mode of action to Trusitev SR (cholinergic properties). The reduction in gastric motility caused by antimuscarinics may affect the absorption of other drugs.

Trusitev SR with food
Trusitev SR can be taken before, after or during a meal.

Pregnancy and breast-feeding
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.

<u>Pregnancy</u>
You should not take Trusitev SR when you are pregnant.

<u>Breast-feeding</u>
It is not known if tolterodine, the active substance of Trusitev] SR, is excreted in the mother's breast milk. Breast-feeding is not recommended during administration of Trusitev] SR.

Driving and using machines
Trusitev SR may make you feel dizzy, tired or affect your sight. If you experience any of these effects then you should not drive your car or operate heavy machinery.

Trusitev SR contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains less than 1 mmol sodium (23 mg) per prolonged-release capsule, that is to say essentially 'sodium-free'.

3. How to take Trusitev SR

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

Adults
The recommended dose is one 4 mg prolonged-release hard capsule daily.

Patients with liver or kidney problems
In patients with liver or kidney problems your doctor may reduce your dose to 2 mg Trusitev SR daily.

Use in children
Trusitev SR is not recommended for children.

Method of administration
The prolonged-release capsules, hard are for oral use and should be swallowed whole.
Do not chew the capsules.

Duration of treatment
Your doctor will tell you how long your treatment with Trusitev SR will last. Do not stop treatment early because you do not see an immediate effect. Your bladder will need some time to adapt. Finish the course of prolonged-release capsules prescribed by your doctor. If you have not noticed any effect by then, talk to your doctor. The benefit of the treatment should be re-evaluated after 2 or 3 months.

If you take more Trusitev SR than you should
If you or somebody else takes too many prolonged-release capsules, contact your doctor or pharmacist immediately. Symptoms in case of overdose include hallucinations, excitation, a heartbeat faster than usual, dilation of the pupil and inability to urinate or breathe normally.

If you forget to take Trusitev SR
If you forget to take a dose at the usual time, take it as soon as you remember unless it is almost time for your next dose. In that case, omit the forgotten dose and follow the normal dose schedule.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Trusitev SR
Always consult your doctor if you are thinking of 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.

You should see your doctor immediately or go to the casualty department if you experience symptoms of

angioedema, such as:
- swollen face, tongue or pharynx
- difficulty to swallow
- hives and difficulty in breathing

You should also seek medical attention if you experience a hypersensitivity reaction (for example itching, rash, hives, difficulty breathing). This occurs uncommonly (may affect up to 1 in 100 people).

Tell your doctor immediately or go to the casualty department if you notice any of the following:
- chest pain, difficulty breathing or getting tired easily (even at rest), difficulty breathing at night, swelling of the legs.

These may be symptoms of heart failure. This occurs uncommonly (may affect up to 1 in 100 people).

The following side effects have been observed during treatment with Trusitev SR with the following frequencies.

Very common side effects (may affect more than 1 in 10 people) are:
- Dry mouth

Common side effects (may affect up to 1 in 10 people) are:
- Sinusitis
- Dizziness, sleepiness, headache
- Dry eyes, blurred vision
- Difficulty with digestion (dyspepsia), constipation, abdominal pain, excessive amounts of air or gases in the stomach or the intestine
- Painful or difficult urination
- Diarrhoea
- Extra fluid in the body causing swelling (e.g. in the ankles)
- Tiredness

Uncommon side effects (may affect up to 1 in 100 people) are:
- Allergic reactions
- Heart failure
- Nervousness
- Irregular heartbeat, palpitations
- Chest pain
- Inability to empty the bladder
- Sensation of pins and needles in the fingers and toes
- Vertigo
- Memory impairment

Additional reactions reported include severe allergic reactions, confusion, hallucinations, increased heart rate, flushed skin, heart burn, vomiting, angioedema, dry skin, and disorientation. There have also been reports of worsening symptoms of dementia in patients being treated for dementia.

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 Trusitev SR

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 label/carton. The expiry date refers to the last day of that month.

Do not store above 25°C.

HDPE bottle: Shelf life after first opening is 200 days.

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 Trusitev SR contains

The active substance is tolterodine tartrate.
Each prolonged-release capsule, hard contains 2 mg of tolterodine tartrate, equivalent to 1.37mg of tolterodine.
Each prolonged-release capsule, hard contains 4 mg of tolterodine tartrate, equivalent to 2.74 mg of tolterodine.

The other ingredients are:
Lactose monohydrate, cellulose microcrystalline, poly(vinyl acetate), povidone, silica, sodium laurilsulfate, sodium docusate, magnesium stearate, hydroxypropylmethylcellulose.
2 mg
Capsule composition: indigo carmine (E132), quinoline yellow (E104), titanium dioxide (E171), gelatin.
4 mg
Capsule composition: indigo carmine (E132), titanium dioxide (E171), gelatin.
Inner tablet coating: ethylcellulose, triethyl citrate, methacrylic acid - ethyl acrylate copolymer, 1,2-Propylene glycol.

What Trusitev SR looks like and contents of the pack

Trusitev SR is a prolonged-release capsule, hard designed for once daily dosing.
Trusitev SR 2 mg prolonged-release capsules, hard are opaque green-opaque-green.
Trusitev SR 4 mg prolonged-release capsules, hard are light blue-opaque-light blue opaque.

Trusitev SR 2 mg prolonged-release capsules, hard are available in the following pack sizes:
Blister packs containing: 7, 14, 28, 30, 49, 50, 80, 84, 90, 98, 100, 160, 200, 280 prolonged-release capsules, hard.
HDPE bottles containing: 30, 60, 100, 200 prolonged-release capsules, hard.

Trusitev SR 4 mg prolonged-release capsules, hard are available in the following pack sizes:
Blister packs containing: 7, 14, 28, 30, 49, 50, 80, 84, 90, 98, 100, 160, 200, 280 prolonged-release capsules, hard.
HDPE bottles containing: 30, 60, 100, 200 prolonged-release capsules, hard.

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer

Marketing authorisation holder:
Teva Pharma B.V.,
Swensweg 5,
2031GA Haarlem,
The Netherlands.

Manufacturer:
Pharmathen International S.A ,
Sapes Industrial Park, Block 5,
69300 Rodopi, Greece

TEVA Pharmaceutical Works
Private Limited Company
Pallagi út 13, 4042 Debrecen
Hungary

Pharmachemie B.V.
Swensweg 5,
2031 GA Haarlem
The Netherlands

Teva Operations Poland Sp. z.o.o
ul. Mogilska 80. 31-546, Krakow
Poland

Pharmathen S.A
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153 51 Pallini Attiki
Greece

Pharmadox Healthcare Ltd
KW20A Kordin Industrial Park
Malta

Pharmacare Premium Ltd
HHF 003
Hal Far Industrial Estate
Malta

Merckle GmbH
Ludwig-Merckle Strasse 3
89143 Blaubeuren
Germany

Teva Pharma B.V.
Swensweg 5
2031GA Haarlem
The Netherlands

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

United Kingdom: Mariosea XL Prolonged-release Capsules, hard

Sweden: Tolterodine Teva

Denmark: Tolterodintartrat Teva

Ireland: Trusitev SR prolonged-release capsules, hard

The Netherlands: Tolterodinetartraat retard Teva, capsules met verlengde afgifte

Belgium: Tolterodine Teva Retard capsules met verlengde afgifte, hard

Germany: Tolterodin-ratiopharm 4 mg Retardkapseln

Spain: Tolterodina Teva capsulas duras de liberacion prolongada EFG

Finland: Tolterodin ratiopharm

Luxembourg: Tolterodin-ratiopharm Retardkapseln

Poland: Defur

This leaflet was last revised in January 2023.