Package leaflet: Information for the user
Santizor XL 4mg 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 Santizor XL is and what it is used for

Santizor XL contains the active substance tolterodine. Tolterodine belongs to a class of medicinal products called antimuscarinics.
Santizor XL 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 Santizor XL

Do not take Santizor XL

- If you are allergic (hypersensitive) 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).
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Warnings and precautions
Talk to your doctor or pharmacist before taking Santizor XL

- 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 neuronal disorders that affect your blood pressure, bowel or sexual function (any neuropathy of the autonomic nervous system)
- If you have a hiatal 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.

Children and adolescents
Efficacy of Santizor XL has not been demonstrated in children. Therefore, Santizor XL is not recommended for children.

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

Tolterodine, the active substance of Santizor XL, may interact with other medicinal products.

It is not recommended to use tolterodine in combination with:

- some antibiotics (containing e.g. erythromycin, clarithromycin)
- medicinal products used for the treatment of fungal infections (containing e.g. ketoconazole, itraconazole)
- medicinal products used for the treatment of HIV.

Santizor XL 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 Santizor XL (antimuscarinic properties) or medicines with an opposite mode of action to Santizor XL (cholinergic properties).

Santizor XL with food and drink
Santizor XL 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.

Pregnancy
You should not use Santizor XL when you are pregnant.

Breast-feeding
It is not known if tolterodine, the active substance of Santizor XL, is excreted in the mother's breast milk. Breast-feeding is not recommended during administration of Santizor XL.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Santizor XL may make you feel dizzy, tired or affect your sight**;** your ability to drive or operate machinery may be affected.

Santizor XL contains sucrose (a type of sugar)
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 Santizor XL

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

The recommended dose is one 4 mg prolonged-release capsule daily, except for patients who have a kidney or a liver condition or troublesome side effects, in which case your doctor may reduce your dose to 2 mg tolterodine tartrate daily.

Method of administration:
The prolonged-release capsules 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 Santizor XL 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 Santizor XL than you should
If you or somebody else takes too many prolonged-release capsules, contact your doctor or pharmacist immediately.

If you forget to take Santizor XL
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 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 Santizor XL with the following frequencies.

Very common: may affect more than 1 in 10 people

- Dry mouth

Common: may affect up to 1 in 10 people

- 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
- Tiredness
- Extra fluid in the body causing swelling (e.g. in the ankles)
- Diarrhoea

Uncommon: may affect up to 1 in 100 people

- Allergic reactions
- Nervousness
- Sensation of pins and needles in the fingers and toes
- Vertigo
- Palpitations, heart failure, irregular heartbeat
- Inability to empty the bladder
- Chest pain
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Santizor XL

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, bottle label and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25^{o}C.

Bottle: Store in the original container in order to protect from light.

Blisters: Keep the blister in the outer carton in order to protect from light.

Do not use this medicine if you notice the capsules are damaged.

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 Santizor XL contains
The active substance is tolterodine.
Each capsule contains 4 mg tolterodine tartrate, equivalent to 2.74 mg of tolterodine.

The other ingredients are:
Capsule contents: Sugar spheres (containing sucrose and maize starch) [see section 2 Tolterodin Pfizer contains sucrose (a type of sugar)], hypromellose, ethylcellulose, medium chain triglycerides and oleic acid.

Capsule shell: Gelatine and colorants.

Colorants:
Blue 4 mg prolonged-release capsule: Indigo carmine (E132) and titanium dioxide (E171).

Printing ink: Shellac glaze (E904), titanium dioxide (E171), propylene glycol (E1520) and simeticone.

What Santizor XL looks like and contents of the pack
Santizor XL is a hard prolonged-release capsule designed for once daily dosing.

Santizor XL 4 mg prolonged-release capsules are blue and marked with white printing (symbol and 4).

Santizor XL 4 mg prolonged-release capsules are available in blister packs of 7, 14, 28, 49, 84, 98 and 280 capsules.
And bottles containing 30, 100 and 200 capsules.
Hospital packs are available in packs of 80, 160 and 320 capsules.
Not all pack sizes may be marketed.

Marketing authorisation holder and Manufacturer
Marketing authorisation holder:
Upjohn UK Limited
Ramsgate Road
Sandwich
Kent
CT13 9NJ
United Kingdom

Manufacturer:
Pfizer Italia S.r.l
Località Marino del Tronto
63100 Ascoli Piceno
Italy

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:
Tolterodine Viatris - Netherlands
Tolterodin Pfizer –Finland
Tolterodin Upjohn - Sweden
Santizor – Greece, Austria

Santizor XL 4mg prolonged-release capsules, hard – United Kingdom (Northern Ireland)

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