

Package leaflet: Information for the patient

**MARIOSEA XL 2 mg AND 4 mg PROLONGED-RELEASE CAPSULES
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.

In this leaflet:

1. **What Mariosea XL Prolonged-release Capsules are and what they are used for**
2. **What you need to know before you take Mariosea XL Prolonged-release Capsules**
3. **How to take Mariosea XL Prolonged-release Capsules**
4. **Possible side effects**
5. **How to store Mariosea XL Prolonged-release Capsules**
6. **Contents of the pack and other information**

1. WHAT MARIOSEA XL PROLONGED-RELEASE CAPSULES ARE AND WHAT THEY ARE USED FOR

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

Mariosea 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 MARIOSEA XL PROLONGED-RELEASE CAPSULES

Do not take Mariosea XL if you:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Mariosea XL if you:

- have difficulties in passing urine and/or a poor stream of urine
- have a gastro-intestinal disease that affects the passage and/or digestion of food

- suffer from kidney problems (renal insufficiency)
- have a liver condition
- suffer from neurological disorders that affect your blood pressure, bowel or sexual function (any neuropathy of the autonomic nervous system)
- have a hiatus hernia (herniation of an abdominal organ)
- ever experience decreased bowel movements or suffer from severe constipation (decreased gastro-intestinal motility)
- 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
- have abnormally low levels of potassium (hypokalaemia), calcium (hypocalcaemia) or magnesium (hypomagnesaemia) in your blood.

Other medicines and Mariosea XL

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

Tolterodine, the active substance of Mariosea XL, may interact with other medicines.

It is not recommended to take Mariosea XL 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.

Mariosea 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 Mariosea XL (antimuscarinic properties) or medicines with an opposite mode of action to Mariosea XL (cholinergic properties). The reduction in gastric motility caused by antimuscarinics may affect the absorption of other drugs.

Mariosea XL with food

Mariosea 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 take Mariosea XL when you are pregnant.

Breast-feeding

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

Driving and using machines

Mariosea XL may make you feel dizzy, tired or affect your sight. If you experience any of these

Mariosea XL 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 MARIOSEA XL PROLONGED-RELEASE CAPSULES

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 Mariosea XL daily.

Use in children

Mariosea XL 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 Mariosea 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 Mariosea XL 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 Mariosea 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 stop taking Mariosea XL

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

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 Mariosea XL 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 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 or search for MHRA Yellow Card in the Google Play or

this medicine.

5. HOW TO STORE MARIOSEA XL PROLONGED-RELEASE CAPSULES

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 Mariosea XL Prolonged-release Capsules contains

The active substance is tolterodine tartrate.

Each 2 mg prolonged-release capsule, hard contains 2 mg of tolterodine tartrate, equivalent to 1.37 mg of tolterodine.

Each 4 mg 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 Mariosea XL Prolonged-release Capsules look like and contents of the pack

Mariosea XL Prolonged-release Capsules are prolonged-release capsule designed for once daily dosing.

Mariosea XL 2 mg Prolonged-release Capsules are opaque green-opaque green.

Mariosea XL 4 mg Prolonged-release Capsules are light blue-opaque-light blue opaque.

Mariosea XL Prolonged-release Capsules 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.

HDPE bottles containing: 30, 60, 100, 200 capsules.

Not all pack sizes may be marketed.

TEVA UK Limited, Eastbourne, BN22 9AG, United Kingdom.

Manufacturer

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

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

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

Portfarma ehf
Borgartúni 26, 105 Reykjavík
Iceland

Pharmacare Premium Ltd
HHF 003, Hal Far Industrial Estate,
Malta

Pharmadox Healthcare Ltd
KW20A Kordin Industrial Park
Malta

BioCentrum Sp. z o.o
Bobrzyńskiego 14, 30-348 Krakow
Poland

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

Pharmathen S.A
6, Dervenakion Str., 153 51 Pallini, Attikis
Greece.

This leaflet was last revised in January 2021.

PL 00289/1772
PL 00289/1773