

Package leaflet: Information for the patient

Contiflo XL 400 micrograms Prolonged release capsules

tamsulosin hydrochloride

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 Contiflo XL is and what it is used for
2. What you need to know before you take Contiflo XL
3. How to take Contiflo XL
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1. What Contiflo XL is and what it is used for

The active ingredient in Contiflo XL is tamsulosin. This is a selective $\alpha_{1A/1D}$ -adrenoceptor antagonist. It reduces tension of the smooth muscles in the prostate and the urethra, enabling urine to pass more readily through the urethra and facilitating urination. In addition, it diminishes sensations of urge.

Contiflo XL is used in men for the treatment of the complaints of the lower urinary tract associated with an enlarged prostatic gland (benign prostatic hyperplasia) These complaints may include difficulty urinating (poor stream), dribbling, urgency and having to urinate frequently at night as well as during the day.

2. What you need to know before you take Contiflo XL

Do not take Contiflo XL:

- if you are allergic to tamsulosin hydrochloride or any of the other ingredients of this medicine (listed in section 6). Hypersensitivity may present as sudden local swelling of the soft tissues of the body (e.g. the throat or tongue), difficult breathing and/or itching and rash (angioedema).
- if you suffer from severe liver problems.
- if you suffer from fainting due to reduced blood pressure when changing posture (going to sit or stand up) or you feel dizzy.

Warnings and precautions

Talk to your doctor or pharmacist before taking Contiflo XL.

- Periodic medical examinations are necessary to monitor the development of the condition you are being treated for.
- Before starting treatment you should tell your doctor if you are suffering from any other disease.
- Rarely, fainting can occur during the use of Contiflo XL as with other medicinal products of this type.
At the first signs of dizziness or weakness you should sit or lie down until they have disappeared.
- if you suffer from severe kidney or liver problems, tell your doctor.
- if you are undergoing or have been scheduled for eye surgery because of cloudiness of the lens (cataract) or increased pressure in the eye (glaucoma), please inform your eye specialist that you have previously used, are using , or are planning to use Contiflo XL can may cause complications (intraoperative Floppy Iris Syndrome [IFIS]) during the surgery. 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 a cataract- or glaucoma surgery because of a cloudy lens.

Children and adolescents

Do not give this medicine to children or adolescent under 18 years because it does not work in this population.

Other medicines and Contiflo XL

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

In particular tell your doctor or pharmacist if you are taking:

- Diclofenac (an anti-inflammatory painkiller) and warfarin (used to prevent blood clotting).
- Medicines to potentially influencing the blood level of tamsulosin such as verapamil or diltiazem (used to lower your blood pressure), ritonavir and indinavir (used to treat HIV infection), ketoconazole, itraconazole or erythromycin (used to treat fungal or bacterial infection).

Taking Contiflo XL together with other medicines from the same class (α_1 -adrenoceptor antagonists such as doxazosin, indoramin, prazosin or alfuzosin) may cause an unwanted decrease in blood pressure.

It is especially important to inform your doctor if you are being treated at the same time with medicines that may decrease the removal of Contiflo XL from the body (for example, ketoconazole, erythromycin).

You should only take medicine concomitantly with Contiflo XL if your doctor allows it.

Contiflo XL with food, drink and alcohol

Contiflo XL must be taken after breakfast or the first meal of the day.

Pregnancy, breast-feeding and fertility

This section is not relevant, because Contiflo XL is not indicated for use in women.

Impaired sexual functions in males have been reported with Contiflo XL.

Driving and using machines

There is no evidence that Contiflo XL affects the ability to drive or to operate machinery or equipment.

However, you should bear in mind that dizziness can occur, in which case you should not undertake activities that require attentiveness.

Contiflo XL contains orange yellow S, azorubine and ponceau 4R

Allergic reactions may occur due to the presence of colouring agents used in this product: orange yellow S (E110), azorubine (E122) and ponceau 4R (E124).

Contiflo XL contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, hard, that is to say essentially 'sodium-free'.

3. How to take Contiflo XL

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

The dosage is one capsule per day to be taken after breakfast or the first meal of each day. The capsule should be taken while standing or sitting (not lying down) with a glass of water. The capsule is to be swallowed whole and must not be crushed or chewed, as this would impair the delayed release of the active ingredient. Usually, Contiflo XL is prescribed for long periods of time. The effects on the bladder and on urination are maintained during long-term treatment with Contiflo XL.

If you take more Contiflo XL than you should

Taking too many capsules of Contiflo XL may lead to an unwanted decrease in blood pressure and an increase in heart rate, with feelings of faintness. Contact your doctor immediately if you have taken too much Contiflo XL.

If you forget to take Contiflo XL

You may take your daily Contiflo XL later the same day if you have forgotten to take it as recommended. If you have missed a day, just continue to take your daily capsule as prescribed. Do not take a double dose to make up for a forgotten capsule.

If you stop taking Contiflo XL

When treatment with Contiflo XL is stopped prematurely, your original complaints may return. Therefore use Contiflo XL as long as your doctor prescribes, even if your complaints have disappeared already. Always consult your doctor, if you consider stopping this therapy.

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.

Serious side effects are rare or very rare. Stop taking this medicine and see a doctor straight away if you experience any of the following symptoms - you may need medical treatment:

- Sudden local swelling of soft tissues (e.g., throat or tongue), difficulty breathing, and/or itching and skin rash, often in the form of an **allergic reaction** (angioedema) (may affect up to 1 in 1,000 people)
- priapism (painful, persistent, involuntary erection of the penis), in which case immediate medical aid is needed (may affect up to 1 in 10,000 people)
- a severe inflammatory eruption of the skin and mucous membranes, which is an allergic reaction to drugs or other substances called Stevens-Johnson syndrome, (may affect up to 1 in 10,000 people)
- serious skin rashes (erythema multiforme, dermatitis exfoliative) (frequency cannot be estimated from the available data).

The following side effects have also been reported:

Common (may affect up to 1 in 10 people):

- Dizziness, particularly when going to sit or stand up.
- Ejaculation disorders
- Retrograde ejaculation; this means that semen does not leave the body via the urethra, but instead goes into the bladder. This phenomenon is harmless.
- Ejaculation failure.

Uncommon (may affect up to 1 in 100 people):

- Headache
- palpitations (the heart beats more rapidly than normal and it is also noticeable)
- reduced blood pressure e.g. when getting up quickly from a seating or lying position sometimes
- associated with dizziness
- runny or blocked nose (rhinitis)
- diarrhoea, feeling sick and vomiting
- constipation, weakness (asthenia), rashes, itching and hives (urticaria).

Rare (may affect up to 1 in 1000 people):

- fainting
- weakness

Not known (frequency cannot be estimated based on available data)

- Vision blurred, visual impairment
- Nose bleed
- Dry mouth
- Abnormal irregular heart rhythm (atrial fibrillation, arrhythmia, tachycardia), difficult breathing (dyspnoea).
- If you are undergoing eye surgery because of cloudiness of the lens (cataract) and are already taking or have previously taken Contiflo XL, the pupil may dilate poorly and the iris (the coloured circular part of the eye) may become floppy during the procedure.

If you have to undergo eye surgery due to a clouding of the lens (cataract) or increased intraocular pressure (glaucoma) and are taking or have recently taken Contiflo XL, insufficient dilation of the pupil and drooping of the iris (the colored circular part of the eye) may occur during surgery.

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 the Yellow Card Scheme at: 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 Contiflo XL

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions

Do not use this medicine after the expiry date which is stated on the carton and label. The expiry date refers to the last day of that month.

Never dispose of medicines in the wastewater (e.g. not in the toilet or sink). Ask your pharmacy how to dispose of the medicine when you are no longer using it. By doing so, you will help protect the environment.

6. Contents of the pack and other information

What Contiflo XL contains

The active substance is tamsulosin hydrochloride. One prolonged release capsule contains 400 micrograms of tamsulosin hydrochloride.

The other ingredients are: capsule contents: cellulose microcrystalline PH101, magnesium stearate, methacrylic acid-ethyl acrylate copolymer (1:1) dispersion, sodium hydroxide, triacetin, titanium dioxide (E171), purified talc.

Capsule body: gelatine, orange yellow S (E110), ponceau 4R (E124), quinoline yellow (E104), brilliant blue (E133), titanium dioxide (E171).

Cap composition: gelatine, yellow iron oxide (E172), brilliant blue (E133), azorubine (E122), titanium dioxide (E171).

Printing ink: shellac, black iron oxide (E172), potassium hydroxide.

What Contiflo XL looks like and contents of the pack

Contiflo XL 400 micrograms prolonged release capsules comprise of light Brown cap/Orange body of size '2' imprinted with 'R' on cap and 'TSN400' on body in black edible ink containing white to off-white granules.

Packs of 1, 2, 4, 7, 10, 14, 20, 28, 30, 50, 56, 60, 90, 98,100 or 200 prolonged release capsules.

Not all pack sizes may be marketed.

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