

Xalgetz™

(TAMSULOSIN HCl CAPSULES USP)

0.4mg Modified-Release Capsules

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

WHAT IS IN THIS LEAFLET

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WHAT XALGETZ IS AND WHAT IT IS USED FOR

Xalgetz contains the active substance tamsulosin hydrochloride. This active substance 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.

Xalgetz is used in men for the treatment of the complaints of the lower urinary tract associated with an enlarged prostate (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.

BEFORE YOU USE XALGETZ

Do not take or use Xalgetz

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

Before you start to use Xalgetz

Talk to your doctor or pharmacist before taking Xalgetz:

- Periodic medical examinations are necessary to monitor the development of the condition you are being treated for.
- Rarely, fainting can occur during the use of tamsulosin, 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 problems, tell your doctor.
- If you are undergoing or have been scheduled for eye surgery because of cloudiness of the lens (cataract) or increased internal pressure of the eye (glaucoma), please inform your eye specialist that you are using or have previously used Xalgetz. This is because Xalgetz may cause complications 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 eye surgery.

Children and adolescents

Do not give this medicine to children or adolescent under 18 years because there is no relevant indication for use of Xalgetz in this age group and its efficacy has not been established in this population.

Taking or using other medicines

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

Certain medicines (e.g., medicines preventing blood clotting called anticoagulants such as warfarin, anti-inflammatory drugs such as

diclofenac) can influence the effects of tamsulosin. Therefore, you can only take medicines concomitantly with Xalgetz if your doctor allows it.

Taking or using Xalgetz with food and drink

Take Xalgetz (Tamsulosin hydrochloride) with a glass of water after breakfast or after your first meal of the day.

Pregnancy, breast-feeding and fertility

Xalgetz is not indicated for use in women.

In men, abnormal ejaculation has been reported (ejaculation disorder). This phenomenon is harmless.

Driving and using machines

Xalgetz can adversely affect the ability to drive or operate machines. It should be taken into account that in some patients dizziness may occur.

HOW TO USE XALGETZ

Use Xalgetz as directed by your doctor or pharmacist.

How to take or use

Do not crush or chew the capsule, swallow it whole with a glass of water.

How often to use

If it is not prescribed otherwise by your doctor the recommended dose is one capsule daily, to be taken after breakfast or the first meal of the day.

How long to use

Use Xalgetz as long as your doctor prescribes, even if your complaints have disappeared already.

If you forget to use it

Take the forgotten capsule on the same day. However, on the next day do not take a double dose to make up for a forgotten dose; just resume treatment at one capsule a day.

If you use too much (overdose)

Taking more Xalgetz may lead to unexpected drop of blood pressure and rapid heartbeat, followed by dizziness. Contact your doctor immediately or visit the emergency department of the nearest hospital as the consequences of accidental or deliberate overdose may require medical intervention.

If you stop taking Xalgetz

You should not stop taking it without consulting your doctor before. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Do not be alarmed by this list of possible side effects, you may not have any of them. Most patients do not notice any side effects. However if you do and they bother you, talk to your doctor.

- If you begin to feel light-headed or dizzy, sit or lie down until you feel better.

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

- dizziness, especially when you are getting up from a chair or bed
- ejaculation disorders

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

- headache
- rapid heartbeat
- dropping of blood pressure especially when standing up
- obstructed or runny nose
- constipation
- diarrhoea
- nausea
- vomiting
- rash
- nettle rash
- itching
- weakness

Rare (may affect up to 1 in 1,000 people):

- fainting
- swelling of the lower layers of the skin, often around the mouth or of the mucosa of the mouth or throat which can appear very quickly

Very rare (may affect up to 1 in 10,000 people):

- priapism (painful, persistent, involuntary erection of the penis), in which case immediate medical aid is needed
- severe inflammatory eruption of the skin and mucous membranes, which is an allergic reaction to drugs or other substances called Stevens-Johnson syndrome.

If you are undergoing eye surgery because of cloudiness of the lens (cataract) or increased internal pressure of the eye (glaucoma) and are already taking or have previously taken tamsulosin hydrochloride, the pupil may dilate poorly and the iris (the colored circular part of the eye) may become floppy during the procedure.

HOW TO STORE XALGETZ

Storage:

- Do not store above 30°C.
- Protect from sunlight and moisture.
- Keep out of reach and sight of children.

How to check the expiry date of medicine

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

Disposal

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.

FURTHER INFORMATION

Product Description:

What Xalgetz looks like:

Xalgetz Capsules 0.4mg are Hard gelatin capsules with standard grey opaque cap and caramel opaque body printed Getz logo on cap and 0.4 on shell containing white to off white spherical pellets.

Ingredient:

Active ingredient:

Tamsulosin hydrochloride.

In-active Ingredients:

Empty Gelatin capsules Size# 2

Meets USP Dissolution Test 2

DATE OF PREPARATION

October 04, 2016



Manufacturer and Product Registration Holder:
Getz Pharma (Pvt.) Ltd. 29-30/27, Korangi Industrial Area, Karachi - 74900, Pakistan.

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