

Package leaflet: Information for the patient

TEVAX 10 mg, prolonged release tablets

Alfuzosin hydrochloride

Read all of this leaflet carefully before you start using 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 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 TEVAX 10 mg is and what it is used for
2. What you need to know before you take TEVAX 10 mg
3. How to take TEVAX 10 mg
4. Possible side effects
5. How to store TEVAX 10 mg
6. Contents of pack and other information

1. What TEVAX 10 mg is and what it is used for

This drug belongs to the group of medicines called alpha-blockers.

It is used to treat moderate to severe symptoms caused by an enlarged prostate gland, a condition that is also called benign prostatic hyperplasia. Enlarged prostate glands can cause urinary problems such as frequent and difficult urination.

2. What you need to know before you take TEVAX 10 mg

Do not take TEVAX 10 mg, prolonged release tablets:

- if you are allergic to alfuzosin, other quinazoline (e.g. terazosin, doxazosin) or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from conditions that cause a marked drop in blood pressure when standing up;
- if you have hepatic impairment (liver function disorder);
- if you are taking other medicines belonging to the group called alpha1-blockers (e.g. tamsulosin).

Warnings and precautions

Talk to your doctor or pharmacist before taking TEVAX 10 mg,

- if you have severe kidney problems.
- if you take other medicines to treat high blood pressure. In this case your doctor will check your blood pressure regularly, especially at the beginning of treatment.
- if you experience a sudden drop in blood pressure when you stand up shown by dizziness, weakness or sweating within a few hours after you have taken TEVAX 10 mg. If you experience a drop in blood pressure you should lie down with your legs and feet up in the air until the symptoms have disappeared. Usually, these effects last for only a short time and occur at the start of the treatment. Normally, there is no need to stop treatment.

- if you experience a marked drop in blood pressure in the past after taking another medicine belonging to the group of alpha-blockers. In this case your doctor will start treatment with alfuzosin at low doses and will gradually increase the dose.
- if you suffer from acute heart failure.
- if you suffer from chest pain (angina) and are treated with a nitrate as this may increase the risk of a drop in blood pressure. You should discuss with your doctor whether to continue or stop your treatment with TEVAX 10 mg, especially when the chest pain recurs or worsens.
- if you have an abnormal heart rhythm called QTc prolongation (long QT) or you are taking medicines likely to increase the risk of QTc prolongation. Tell your doctor if you suffer from this condition or are taking any other medicines.
- if you are over 65. This is due to the increased risk of developing low blood pressure (hypotension) and related side effects in elderly patients.
- if you are undergoing eye surgery because of cataract (cloudiness of the lens) please inform your eye specialist before the operation that you are using or have previously used TEVAX 10 mg. This is because TEVAX 10 mg may cause complications during the surgery which can be managed if your specialist is prepared in advance.

Other medicines and TEVAX 10 mg:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

TEVAX 10 mg and some medicines may interfere with each other. These include:

- other medicines that belong to the group of alpha-blockers: you must not take such medicines at the same time as TEVAX 10 mg (see "Do not take TEVAX 10 mg, prolonged release tablets" above)
- ketoconazole and itraconazole (medicines used to treat fungal infections) and ritonavir (medicine used to treat HIV)
- certain antibiotic drugs (clarithromycine, erythromycine)
- medicines you receive before an operation (general anaesthetics). Your blood pressure can drop markedly. If you have to undergo an operation, please tell the doctor that you are taking TEVAX 10 mg.

TEVAX 10 mg, prolonged release tablets with food and drink

The tablet can be taken with or without food.

Pregnancy and breast-feeding

A TEVAX 10 mg is only intended for men.

Driving and using machines

At the beginning of treatment with TEVAX 10 mg may make you feel lightheaded, dizzy or weak. Do not drive or operate machinery or perform any hazardous tasks until you know how your body responds to the treatment. .

Important information about some of the ingredients of TEVAX 10 mg

This medicine contains lactose. 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 TEVAX 10 mg,

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

Posology

The recommended dose is 1 prolonged-release tablet once daily. Take the first tablet at bedtime. Take the tablets immediately after the same meal each day and swallow them whole with a sufficient amount of fluid. Do not crush, chew or divide the tablets.

The posology does not need to be adjusted for elderly (over 65 years).

The usual dose for patients with mild to moderate kidney problems is 1 prolonged release tablet (10 mg alfuzosin). Take the first tablet at bedtime.

TEVAX 10 mg, prolonged release tablets are not intended for use in children or teenagers aged 2 to 16 years as they have not been shown to be effective in these patients.

If you take more TEVAX 10 mg, prolonged release tablets, than you should:

If you take large amounts of TEVAX 10 mg your blood pressure may suddenly drop and you may feel dizzy or even faint. If you begin to feel dizzy, sit or lie down until you feel better. If the symptoms do not disappear, call your doctor as the drop in blood pressure may have to be treated in hospital.

If you forget to take TEVAX 10 mg, prolonged release tablets:

Do not take a double dose to make up for a forgotten tablet as this may cause a sudden drop in blood pressure, especially if you take blood-pressure lowering medicines. Take the next tablet as directed.

If you stop taking TEVAX 10 mg, prolonged release tablets

You should not interrupt or stop taking TEVAX 10 mg without speaking to your doctor first. If you want to stop the treatment or have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

- Dizziness/faintness, headaches;
- Digestive disorders such as nausea, stomach pain, dry mouth;
- Feeling of weakness, malaise.

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

- Drowsiness, fainting, vertigo;
- Visual disturbances,
- Faster heartbeat, palpitations (the heart beats more rapidly than normal and it is also noticeable);
- Fall in blood pressure when moving from a supine to a standing position (especially when starting treatment with a too high dose and when treatment is resumed);
- Flushing
- Rhinitis;
- Diarrhoea;
- Skin disorders such as skin rash or itching, pruritus;
- Redness of the face, oedema, chest pains.

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

- Worsening or recurrence of chest pain (angina pectoris);
- Quincke's oedema (swelling of the face, lips, tongue and/or throat), urticaria

Not known (frequency cannot be estimated from the available data):

- Reduced number of white blood cells (neutropenia), which may lead to more frequent infections than usual;
- Intraoperative Floppy Iris Syndrome (IFIS). If you are undergoing eye surgery because of cataract (cloudiness of the lens) and are using or have previously used alfuzosin, the pupil may dilate poorly and the iris (the coloured circular part of the eye) may become floppy during the procedure. This only occurs during the operation and it is important for the eye specialist to be

- aware of this possibility as the operation may need to be performed differently (see 'Take special care with TEVAX 10 mg, prolonged release tablets' above);
- Abnormal heart rhythm (atrial fibrillation);
 - Being sick (vomiting);
 - Liver problems: signs may include yellowing of your skin or the whites of your eyes;
 - Abnormal, often painful, persistent erection of the penis unrelated to sexual activity (priapism).

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

5. How to store TEVAX 10 mg

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton or blister strips after EXP.

The expiry date refers to the last day of that month

Keep the blister in the outer carton in order to protect from light

Store below 30°C.

For bottles (HDPE):

The shelf life of the product after first opening is 1 year, but no longer than the expiry date stated on the box or bottle after the letters EXP.

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 TEVAX 10 mg, prolonged release tablets contains

The active substance is alfuzosin hydrochloride.

One prolonged release tablet contains 10 mg of alfuzosin hydrochloride.

The other ingredients are lactose monohydrate, hypromellose (E464), povidone K25 and magnesium stearate.

What TEVAX 10 mg, prolonged release tablets looks like and contents of the pack

TEVAX 10 mg is a round white prolonged release tablet in blister strips (PVC/PVDC/aluminium) of 10, 28, 30, 50, 90 or 100 tablets per pack, or bottles (HDPE) of 100 tablets per pack. All pack sizes may not be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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

Manufacturer

PHAST GmbH,
Kardinal-Wendel-Strasse
16, 6642 HOMBURG,
Germany

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

Estonia: ALFUZOSIN-TEVA

France: ALFUZOSINE TEVA LP 10 mg, comprimé à libération prolongée

Greece: Alfuzosin Teva 10mg SR, δισκία παρατεταμένης αποδέσμευσης

Ireland: TEVAX 10 mg, prolonged release tablets

Latvia: Alfuzosin-Teva 10 mg ilgstošās darbības tabletes

Lithuania: Alfuzosin-Teva 10 mg pailginto atpalaidavimo tabletės

Portugal: Alfuzosina Teva 10 mg comprimido de libertação prolongada

Spain: Alfuzosina Teva 10 mg comprimidos de liberación prolongada EFG

United Kingdom: Fuzatal XL 10mg prolonged release tablets

This leaflet was last revised in March 2016.