



PATIENT INFORMATION LEAFLET

Tamurex 400 micrograms prolonged-release capsules Tamsulosin 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 further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should 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.

In this leaflet:

1. What Tamurex is and what it is used for
2. Before you use Tamurex
3. How to use Tamurex
4. Possible side effects
5. How to store Tamurex
6. Further information

1. WHAT TAMUREX IS AND WHAT IT IS USED FOR

Tamurex is used in the treatment of functional symptoms of benign prostatic hyperplasia, such as difficult urination.

The active ingredient of Tamurex is tamsulosin. Tamsulosin is an α_1 -receptor blocker which reduces the tension in muscles of prostate and urethra. Thus an easier flow of urine through the urethra and urination are facilitated.

2. BEFORE YOU USE TAMUREX

Do not use Tamurex:

- if you are hypersensitive (allergic) to tamsulosin or any of the other ingredients of Tamurex.
- if you suffer orthostatic hypotension.
- if you suffer severe hepatic insufficiency.

Take special care with Tamurex:

- if you suffer from orthostatic hypotension (dizziness caused by low blood pressure after sitting or standing up).
- if you take other α_1 -receptor blockers.
- if you suffer from severe renal insufficiency.
- 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 Tamurex. This is because Tamurex may cause complications during the surgery which can be managed if your specialist is prepared in advance.

Using Tamurex with food and drink:

Tamurex should be taken after breakfast or after the first meal of the day with a glass of water.

Pregnancy and breast-feeding

Tamurex is intended for male patients only.

Children:

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

Driving and using machines:

No data is available on whether tamsulosin adversely affects the ability to drive or operate machines. However, in this respect patients should be aware of the fact that Tamurex may cause dizziness.

Using other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed or herbal medicinal products.

Concomitant use of tamsulosin with other α_1 -receptor blockers (prazosin, alfuzocin) may cause hypotension.



3. HOW TO USE TAMUREX

Always use Tamurex as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. The usual dose is one capsule per day.

Tamurex should be taken after breakfast or after the first meal of the day with a glass of water. The capsules should be swallowed whole while sitting or standing (not in lying position). The capsule should not be broken or chewed as this will interfere with the modified release of the active ingredient. The capsule can, however, be opened and the content can be swallowed without chewing.

If you have the impression that the effect of Tamurex is too strong or too weak, talk to your doctor or pharmacist.

If you take more Tamurex than you should:

If you have taken more tamurex than the doctor prescribed, contact your doctor or a hospital.

If you forget to take Tamurex:

If you forget to take the medicine after breakfast, you can take it later the same day. You should skip the dose if you do not notice forgetting it until the following day.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Tamurex can cause side effects. The following adverse reactions have been reported during the use of Tamurex:

Common (more than 1 in 100 treated patients, but fewer than 1 in 10 treated patients): dizziness.

Uncommon (more than 1 in 1,000 treated patients, but fewer than 1 in 100 treated patients): headache, palpitations, dizziness especially when sitting down or standing up from the lying position, rhinitis, gastrointestinal reactions (constipation, diarrhoea, nausea, vomiting), allergic reactions (skin rash, pruritus, urticaria), abnormal ejaculation, weakness.

Rare (more than 1 in 10,000 treated patients, but fewer than 1 in 1,000 treated patients): fainting, angioedema.

Very rare (fewer than 1 in 10,000 treated patients): priapism (persistent and painful erection).

If any of the side effects get serious, or you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE TAMUREX

Store in the original container.

Do not store above 30 °C.

Do not use Tamurex after expiry date which is stated on the label.

Keep out of the reach and sight of children.

6. FURTHER INFORMATION

What Tamurex contains

The active ingredient is tamsulosin as the hydrochloride. Each prolonged-release capsule contains 400 micrograms of tamsulosin hydrochloride.

The other ingredients are

Capsule contents : sodium alginate, methacrylic acid – ethyl acrylate copolymer (1:1), glycerol dibehenate, maltodextrin, sodium laurilsulphate, macrogol 6000, polysorbate 80, sodium hydroxide, simeticone emulsion (*simeticone, methylcellulose, sorbic acid*), colloidal anhydrous silica.

Capsule shell: gelatin, red iron oxide (E172), titanium dioxide (E171), yellow iron oxide (E172)

What Tamurex looks like and contents of the pack

Orange number 2 gelatin capsule which contains white or yellowish granules. Tamurex is available in blister packs of 30 capsules.

Marketing Authorisation Holder:

Strandhaven Ltd t/a Somex Pharma
Seven Kings, Ilford, Essex, IG3 8BS,
United Kingdom

Manufacturer:

Somex Pharma, Seven Kings, Ilford,
Essex IG3 8RA, UK

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

UK Tamurex 400 micrograms prolonged-release capsules

This leaflet was last approved in 07/2012

