

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, frequent trips to the toilet to pass water, a feeling of not completely emptying the bladder and having to get up several times in the night to pass water.

The active ingredient of Tamurex is tamsulosin hydrochloride. Tamsulosin is an alpha 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.

In the prostate gland, bladder and urethra there are specialised cells containing alpha_{1A}-receptors that cause the muscles in the urethra to tighten. Tamsulosin is an alpha_{1A}-adrenoceptor blocker, which reduces the action of these specialised cells and relaxes the muscles making it easier to pass water.

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.
- If you have kidney problems

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 alpha₁-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.

Pregnancy, breast-feeding and fertility

Tamsulosin is not indicated for use in women.

In men, abnormal ejaculation has been reported (ejaculation disorder).

This means that the semen does not leave the body via the urethra, but instead goes into the bladder (retrograde ejaculation) or the ejaculation volume is reduced or absent (ejaculation failure). This phenomenon is harmless.

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, drowsiness, blurred vision and fainting. If you suffer from these do not drive or operate machinery.

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 alpha₁-receptor blockers (prazosin, alfuzocin) may cause hypotension.

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

- Medicines to lower your blood pressure such as verapamil and diltiazem
- Medicines to treat HIV such as ritonavir or indinavir
- Medicines to treat a fungal infection such as ketoconazole or itraconazole
- Other alpha blockers such as doxazosin, indoramin, prazosin or alfuzosin
- Erythromycin, an antibiotic used to treat infections

Please inform your doctor that you are on Tamsulosin before any operation or dental procedure as there is a potential that your medicine may interfere with the effects of the anaesthetic.

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 recommended dose for adults and the elderly is one tablet each day. It can be taken with or without food

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 too many capsules, contact your doctor immediately or go to the nearest hospital casualty department taking any remaining medication and this patient information leaflet with you.

If you forget to take Tamurex:

You may take your capsule later the same day if you have forgotten to take it earlier. If you have missed a day, just continue to

take your daily capsule from the next day. Do not take a double dose to make up for a missed dose.

If you have any further questions on the use of this product, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Tamurex can cause side effects.

Stop taking this medicine and consult your doctor immediately if any of the following occur – you may need medical treatment.

- Allergic reaction - (affects less than 1 in 1,000 people). The signs may include finding it difficult to breathe, having an itchy rash, having a swollen face, throat, or tongue
- Long-lasting and painful erection (usually not during sexual activity) - affects less than 1 in 10,000 people
- A severe skin reaction with symptoms that could include skin blistering and exfoliation (known as Stevens-Johnson syndrome, erythema multiforme, or exfoliative dermatitis). It is very rare, affecting less than 1 in 10,000 people (or of unknown frequency).

The following side effects have also been reported:

Common: may affect up to 1 in 10 people

- abnormal ejaculation - (ejaculation disorder)-this means that semen does not leave the body via the urethra, but instead goes into the bladder (retrograde ejaculation) or the ejaculation volume is reduced or absent (ejaculation failure). This phenomenon is harmless.
- dizziness especially when sitting down or standing up from the lying position.

Uncommon: may affect up to 1 in 100 people

- headache
- palpitations
- rhinitis
- gastrointestinal reactions - (constipation, diarrhoea, nausea, vomiting)
- allergic reactions - (skin rash, pruritus, urticaria)
- abnormal ejaculation
- weakness
- abnormal irregular heart rhythm - (atrial fibrillation, arrhythmia, tachycardia).

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

- fainting
- swelling of the face, throat or tongue with breathing problems linked to allergy.
- syncope - (temporary loss of consciousness caused by a fall in blood pressure)
- angioedema - (swelling of the lower layer of skin and tissue under the skin)

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

priapism (persistent and painful erection usually unrelated to sexual activity).

- Rash, inflammation and blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals (Stevens-Johnson syndrome).

Not known: frequency cannot be estimated from the available data

- blurred vision
- impaired vision
- nose bleeds (epistaxis)
- serious skin rashes (erythema multiforme, dermatitis exfoliative)
- dry mouth

As with other medicines of this type, drowsiness, blurred vision or swelling of the hands and feet can occur.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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.

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 to protect the environment.

6. FURTHER INFORMATION

What Tamurex contains

The active ingredient is tamsulosin 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 laurylsulphate, 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

Manufacture:

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 07/2018