

Faramsil 400 microgram Prolonged-release Tablets

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 Faramsil is and what it is used for
2. What you need to know before you take Faramsil
3. How to take Faramsil
4. Possible side effects
5. How to store Faramsil
6. Contents of the pack and other information

1. What Faramsil is and what it is used for

Faramsil contains the active substance tamsulosin hydrochloride, which belongs to a group of medicines called alpha adrenoceptor blockers.

Tamsulosin relaxes:

- the muscles in the prostate gland, and
 - the tube from the bladder to the outside (the urethra).
- This lets urine pass more easily through the urethra, making it easier to urinate.

Tamsulosin is for men who have benign prostate enlargement (benign prostatic hyperplasia, BPH). This is when the prostate gland increases in size. This can make it difficult to pass urine. This means you may have to pass urine often or during the night. You may also feel that you still need to pass urine even after having done so. You may also dribble after passing urine.

2. What you need to know before you take Faramsil

Do not take Faramsil if

- you are allergic to tamsulosin or any of the other ingredients of this medicine (listed in section 6)
- you have a serious liver problem.
- you feel dizzy or faint when you suddenly sit or stand up.

Warnings and precautions

Talk to your doctor before taking tamsulosin

- if you have a serious kidney problem.

As with other medicines in the same group, dizziness can occur in individual cases, when taking tamsulosin.

If you feel weak or dizzy, when taking tamsulosin, you should sit or lie down straight away until the symptoms have disappeared.

Before you start taking tamsulosin your doctor may need to examine you. This is to check that you do not have another condition with the same symptoms as BPH. Your doctor may also use a blood test before you start taking the medicine. These tests may continue

afterwards, to see how the medicine is working. If you are undergoing eye surgery because of cloudiness of the lens (cataract) or increased pressure in the eye (glaucoma), please inform your eye specialist that you are using or have previously used tamsulosin. 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 because of a cloudy lens (cataract) or increased pressure in the eye (glaucoma).

Children

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

Other medicines and Faramsil

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:

- Medicines that 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 Faramsil before any operation or dental procedure as there is a potential that your medicine may interfere with the effects of the anaesthetic.

Faramsil with food and drink

Tamsulosin can be taken independently of food.

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.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. However you should be aware of the fact that drowsiness, blurred vision, dizziness and fainting can occur. If you feel weak or dizzy, do not drive or use machines.

Faramsil contains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. This medicine contains less than 1 mmol (23 mg) sodium per film-coated prolonged-release tablet, that is to say essentially 'sodium-free'.

3. How to take Faramsil

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is one tablet each day. It can be taken with or without food. Swallow the tablet whole. Do not crush or chew it.

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If you take more Faramsil than you should

- Talk to your doctor or pharmacist or go to the nearest hospital straight away.
- Take this leaflet and any of the remaining tablets with you.

Taking too much Faramsil may make you feel dizzy or faint and cause headache.

If you forget to take Faramsil

If you forget to take your Faramsil at your usual time, take it later the same day.

If you miss a whole day, just take your normal tablet the next day. Do not take a double dose to make up for a forgotten dose.

If you stop taking Faramsil

If you stop taking Faramsil your original symptoms may return. You should keep taking Faramsil as advised by your doctor, even if your symptoms have gone away. Always talk to your doctor if you are thinking about stopping taking this medicine.

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.

You should contact your doctor immediately if you notice any of the following side effects (it may be an allergic reaction):

- lumpy skin rash (urticaria)
- swollen feet, hands, lips, tongue or throat and difficulty breathing.

Stop taking this medicine and see a doctor straight away if you experience any of the following symptoms - you may need medical treatment:

- serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome)
- rash, inflammation and blistering of the skin (erythema multiforme, dermatitis exfoliative)

If you feel weak or dizzy, when taking tamsulosin, you should sit or lie down straight away until the symptoms have disappeared.

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

- feeling dizzy
- 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.

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

- headache
- fast or uneven heart beat (palpitations)
- a fall in blood pressure on standing up which causes dizziness, light-headedness or fainting
- runny or blocked nose
- feeling sick or being sick
- diarrhoea or constipation
- allergic reactions (skin rash, itchy or inflamed skin)
- feeling weak.

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

- fainting

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

- long-lasting and painful erection (priapism), normally not during sexual activity

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

- irregular heart beat, faster heart beat
- shortness of breath

- vision blurred, visual impairment
- bleeding from the nose
- dry mouth

As with other medicines that belong to the same group (alpha-blockers), tamsulosin can also cause drowsiness, blurred vision, dry mouth or oedema.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system the Yellow Card Scheme (www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in Google play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Faramsil

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

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

Store in the original package.

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. Contents of the pack and other information

What Faramsil contains

- The active substance is tamsulosin hydrochloride.
 - Each film-coated prolonged-release tablet contains 0.4 mg of tamsulosin hydrochloride.
- The other ingredients are:
 - *Tablet core*: cellulose, microcrystalline, hydroxypropylcellulose, lactose monohydrate, polyethylene oxide, butylhydroxytoluene, magnesium stearate, silica, colloidal anhydrous
 - *Tablet film-coating*: hypromellose, hydroxypropylcellulose, macrogol 400, titanium dioxide (E 171), talc, quinoline yellow (contains sodium) (E 104), carmine (E 120), iron oxide, black (E 172).

What Faramsil looks like and contents of the pack

Faramsil are brown, round, biconvex marked "0.4" on one side and "SZ" on the other side.

Faramsil is packed in aluminium/aluminium blisters: 10, 14, 20, 28, 30, 50, 56, 60, 80, 90, 100 or 200 film-coated prolonged-release tablets. Not all pack sizes may be marketed.

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