

TAMSIN FORTE

Tamsulosin hydrochloride prolong released tablets (0.4mg)

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WHAT TAMSIN FORTE IS USED FOR

TAMSIN FORTE is a modified release tablet which contains a medicine called tamsulosin. This belongs to a group of medicines called 'alpha blockers' (or alpha1A-adrenoceptor antagonists).

TAMSIN FORTE is used to treat the lower urinary tract symptoms (LUTS) of a common condition called benign prostatic hyperplasia (BPH). This is when the prostate gland gets bigger. The prostate gland is found just below a man's bladder. When your prostate gland gets bigger, it can:

- Make it difficult for you to start urinating (peeing)
 - Means you take longer or have to urinate more often
 - Lead to the feeling that you still need to urinate again, even though you have just done so
 - Cause you to get up several times in the night to urinate
- TAMSIN FORTE relieves these problems by:

- Relaxing the muscles in the prostate gland
- Relaxing the muscles in the urethra (the tube from the bladder to the outside of the body).

This lets urine pass more freely through the urethra, making it easier to urinate.

HOW TAMSIN FORTE WORKS

Tamsulosin binds selectively and competitively to postsynaptic alpha1-receptors, in particular to the subtype alpha1A, which bring about relaxation of the smooth muscle of the prostate, whereby tension is reduced.

BEFORE YOU USE TAMSIN FORTE

TAMSIN FORTE should be used only by men.

Do not use TAMSIN FORTE if you;

- are allergic to tamsulosin or any of the other ingredients of TAMSIN FORTE
 - have a severe liver condition
 - have ever fainted or felt dizzy when suddenly sitting or standing up.
- Dizziness can sometimes occur when taking TAMSIN FORTE, particularly if you are also taking other alpha1-blockers. If you do feel weak or dizzy make sure you sit or lie down straight away until the symptoms have disappeared.

Pregnancy and breastfeeding

Not applicable, as tamsulosin is intended for male patients only.

Before you start to use it

Do not take **TAMSIN FORTE** if any of the above applies to you, without first consulting your doctor. If you are not sure, talk to your doctor or pharmacist before taking these tablets.

Children and adolescents

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

Taking other medicines

Please tell your pharmacist or doctor if you are taking or have recently taken any other medicines. This includes medicines that you can buy without a prescription, including herbal medicines. This is because TAMSIN FORTE can affect the way some other medicines work and some other

medicines can affect the way TAMSIN FORTE works.

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

HOW TO USE TAMSIN FORTE

How much to use

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

The recommended dose for adults and the elderly is one tablet each day.

It can be taken with or without food. Swallow the tablet whole. Do not chew.

Your doctor may want to examine you from time to time whilst you are taking this medicine.

If you forget to use it

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

If you use too much (overdose)

If you have taken too many tablets, contact your doctor immediately or go to the nearest hospital taking any remaining medication and this patient information leaflet with you.

WHILE YOU ARE USING TAMSIN FORTE

Things you must do

Be alert with TAMSIN FORTE if you:

- Experience dizziness especially after standing up. TAMSIN FORTE may lower your blood pressure, causing these symptoms. You should sit or lie down until the symptoms have gone.
- Suffer from severe kidney problems. The normal dose of TAMSIN FORTE may not have the expected effect when your kidneys are not functioning normally.
- Are undergoing eye surgery because of cloudiness of the lens (cataract). Please inform your eye specialist that you are using or have previously used TAMSIN FORTE. 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.

Things you must not do

- Do not take **TAMSIN FORTE** to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.

Things to be careful of

If you feel weak or dizzy or have blurred vision while taking this medicine, do not drive or use machines.

SIDE EFFECTS

Like all medicines, TAMSIN FORTE may cause side effects, although not everybody gets them.

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

Rare

- Swelling of the face, throat or tongue with breathing problems linked to allergy

Very rare

- Persistent painful erection usually unrelated to sexual activity.
- Rash, inflammation and blistering of the skin and/or lips, eyes, mouth, nasal passages or genitals (Stevens-Johnson syndrome).
- Abnormal irregular heart rhythm (atrial fibrillation, arrhythmia, tachycardia), difficult breathing (dyspnoea).

The following side effects have also been reported:

Common

- dizziness
- abnormal ejaculation. This means that semen does not leave the body via the urethra, but instead goes into the bladder or the ejaculation volume is reduced or absent. This phenomenon is harmless.

Uncommon

- weakness
- headache
- runny or blocked nose
- dizziness as you sit or stand up
- palpitations (rapid or irregular heart beat)
- gastro-intestinal symptoms such as nausea and vomiting, diarrhoea or constipation
- hypersensitivity reactions such as rash, itching, redness, local swelling and breathing problems

Rare

- fainting

Not known:

- blurred vision
- impaired vision
- nose bleeds

- serious skin rashes
- dry mouth

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

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 may report any side effects or adverse drug reactions to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Consumers → Reporting -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

STORAGE AND DISPOSAL OF TAMSIN FORTE

Storage

- Keep your medicine in the original package until it is time to take.
- Keep your medicine in a cool dry place where the temperature stays below 30°C.
- Do not store medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.
- Keep it where children cannot reach it.

Disposal

Ask your pharmacist how to dispose of medicines no longer required or has already expired.

PRODUCT DESCRIPTION

What it looks like

White, un-scored, round tablets with a diameter of 9mm debossed on one side with “T9SL” and “0.4” on the other side.

Ingredients

Each tablet contains:

0.4 mg tamsulosin hydrochloride.

Inactive ingredients are Hypromellose, Microcrystalline Cellulose, Carbomer, Silica colloidal anhydrous, Iron oxide red, Magnesium Stearate & Purified water.

MAL Number: MAL19051008ACZ

MANUFACTURER

Manufactured by:

SYNTHON HISPANIA SL

Castello 1, Poligono las Salinas,
08830 Sant Boi de Llobergat,
Barcelona, Spain

**PRODUCT REGISTRATION
HOLDER**

MEGA LIFESCIENCES SDN BHD
B-28-02, The Ascent, Paradigm,
No.1, Jalan SS7/26A, Kelana Jaya,
47301 Petaling Jaya, Selangor,
Malaysia

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