

FLOMAXTRA®

prolonged release tablets

tamsulosin (tam-su-lo-sin)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FLOMAXTRA.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you having FLOMAXTRA against the benefits they expect it will have for you.

If you have any concerns about this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What FLOMAXTRA is used for

FLOMAXTRA is a medicine for use by MEN only. FLOMAXTRA is used in men who have a medical condition called benign prostatic hyperplasia (also known as BPH). In BPH the prostate gland is bigger than normal. BPH is NOT prostate cancer.

FLOMAXTRA belongs to a group of medicines called alpha-blockers.

Your doctor has prescribed FLOMAXTRA for you because you have symptoms caused by an enlarged prostate gland. BPH occurs only in men. It is common in men over the age of 50 years.

The prostate gland is at the outlet of your urinary bladder. Because your prostate has become bigger than it

should be, it is affecting how well you are able to pass your urine. This causes some, or all of the following symptoms; they usually start gradually and increase in severity:

- Urine flow is slow.
- The urine stream may become a trickle, or it may stop and start.
- You find a delay when you try to pass urine, and you have to strain to do so.
- You feel that you cannot empty your bladder completely.
- You may dribble at the end of passing urine.
- You need to pass urine often during the day.
- You need to get up often during the night to pass urine.
- You feel an urgency to pass urine as soon as you first feel the need to do so.

Ask your doctor if you have any questions about why FLOMAXTRA has been prescribed for you.

Before you take FLOMAXTRA

When you must not take it

FLOMAXTRA is for use by MEN only. If you are a woman or a child, do not take FLOMAXTRA. If you are not sure whether you should start taking FLOMAXTRA you should contact your doctor.

You must not take FLOMAXTRA if:

- you are allergic to any of the ingredients in the tablet (see "Product Description"). Signs of allergic reaction may include a skin rash, itching, shortness of breath or swelling of the face, lips or tongue
- you become dizzy or light-headed or have low blood pressure when you stand up, after sitting or lying down. This is called orthostatic hypotension.
- you have serious liver problems.
- you have serious kidney function problems.
- you are taking other medication which relaxes the smooth muscle of blood vessels (some of the tradenames are Minipress, Prasig, Hytrin).

Do not take FLOMAXTRA if the packaging is torn or shows signs of tampering or the tablets do not look quite right.

Do not take FLOMAXTRA if the expiry date on the pack has passed.

Before you start to take it

Use FLOMAXTRA only if your doctor has prescribed it for you.

All medicines have benefits and risks. In deciding to prescribe FLOMAXTRA for you, your doctor has weighed the risk of taking FLOMAXTRA against the benefit it is expected to have for you.

Your doctor has prescribed FLOMAXTRA for BPH. FLOMAXTRA does not treat prostate cancer. BPH and prostate cancer may have similar symptoms. A man can have prostate cancer and

BPH at the same time. You should be checked for prostate cancer before you start FLOMAXTRA. It is recommended that men be checked for prostate cancer once a year, from 50 years of age onwards. These checks should continue while you are on FLOMAXTRA.

Tell your doctor if you:

- are allergic to FLOMAXTRA or any of its ingredients (see "Ingredients").
- have angina (severe pain in the chest, usually on exertion) or have had a heart attack during the last six months.
- have high, or low blood pressure, or your blood pressure is controlled by medication.
- have had ejaculation problems.
- are suffering from any other illness.
- have any allergies to sulfa or any other medications.

If you are going to have eye surgery for cataracts or glaucoma, please tell your surgeon that you are taking or have taken FLOMAXTRA. (see "Side Effects").

Tell your doctor if you are using any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Your doctor will discuss the risks and benefits of using FLOMAXTRA.

Taking other medicines

Tell your doctor if you are using any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and FLOMAXTRA may interfere with each other. These medicines include:

- cimetidine, a medicine generally used to treat stomach ulcers or reflux.

Taking these medicines with FLOMAXTRA may increase the risk of possible side effects (see Side Effects).

Other medications can also interfere with FLOMAXTRA and make you feel drowsy. Ask your doctor or pharmacist for more information.

How to take FLOMAXTRA

Your doctor will tell you how much you should take, when and how often. It is important that you take this medicine as directed by your doctor.

Do not take FLOMAXTRA if the packaging is torn or shows signs of tampering, or if the tablets show visible signs of deterioration.

If you are unsure ask your doctor or pharmacist.

How much to take

The dose is one tablet a day.

Patients with severe liver problems should not take these tablets.

Patients with severe kidney problems should not take these tablets.

Carefully follow all directions given to you by your doctor and pharmacist.

These directions may differ from the information in this leaflet.

When and how should you take the tablets

The FLOMAXTRA tablet should be swallowed whole, preferably with a glass of water.

Do not crunch, bite or chew the tablet, as this changes how FLOMAXTRA works.

Crunching, biting or chewing the tablet will release the medicine quickly and side effects may then occur.

If you forget to take it

- If it is almost time for your next dose, skip the dose you missed and take your next dose when you

are meant to. Otherwise, take it as soon as you remember, and then go back to taking FLOMAXTRA as you would normally. If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

- If you miss a whole day, just continue to take your normal daily dose the next day.

Do not take a double dose to make up for the dose that you missed.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (13 11 26) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much FLOMAXTRA. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many FLOMAXTRA tablets, this may result in vomiting, diarrhoea and low blood pressure leading to dizziness or fainting.

If you experience any of these symptoms, seek urgent medical attention.

While you are taking FLOMAXTRA

Things you must do

Be sure to keep all of your doctor's appointments so that your progress can be checked.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking FLOMAXTRA.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise your doctor may think it is not working effectively and change your treatment unnecessarily.

If you are going to have eye surgery for cataracts or glaucoma, please tell your surgeon that you are taking or have taken FLOMAXTRA (see "Side Effects").

Things you must not do

Do not give FLOMAXTRA to anyone else, even if they have the same condition as you.

Do not take FLOMAXTRA for any other complaints unless your doctor tells you to.

Things to be careful of

Be careful when driving or operating machinery until you know how FLOMAXTRA affects you.

FLOMAXTRA may cause dizziness and may impair your reactions.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FLOMAXTRA.

Like all medicines, FLOMAXTRA can cause some unwanted side effects in some people. Sometimes they are serious, most of the time they are not. Side effects not listed in this leaflet may occur in some patients. You may need to get medical attention if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Common:

- "retrograde ejaculation". When this happens the ejaculation fluid is not squirted out, most of it runs back into the bladder. Retrograde ejaculation is painless.
- dizziness

Uncommon:

- headache

- skin rash (red spots or patches), itching, hives
- weakness
- dizziness on standing
- nausea, vomiting, diarrhoea, constipation
- fast heart beats
- blocked nose

Rare:

- faintness

FLOMAXTRA can occasionally cause people to feel faint and dizzy. You should get up slowly from the sitting or lying position to reduce the risk of dizziness or light-headedness. If you do feel faint on standing up, you should lie down for a short while. If the dizziness persists you should contact your doctor. You must not drive a car or operate machinery if you feel dizzy.

If you are having an operation on your eyes because of cataracts or glaucoma and are already taking or have taken FLOMAXTRA, the pupil may dilate poorly and the iris (the coloured part of the eye) may become floppy during the procedure. This can be managed if your surgeon knows before carrying out the operation. If you are going to have eye surgery for cataracts or glaucoma, please tell your surgeon that you are taking or have taken FLOMAXTRA.

FLOMAXTRA may also occasionally cause blurred or reduced vision, inflammation and blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals, or nose bleeds.

This is not a complete listing. Other unwanted effects may occur in some men. Tell your doctor if you notice any other effects or if the unwanted effects are particularly bothersome.

You should always tell your doctor about any problems you have whilst taking FLOMAXTRA.

If any of the following happen, tell your doctor or go to accident and

emergency at your nearest hospital immediately:

- extremely rarely, medications similar to FLOMAXTRA have caused prolonged painful erection of the penis, which is unrelated to sexual activity. If you have a prolonged erection, call your doctor or go to the Emergency Room as soon as possible.
- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to FLOMAXTRA. You may need urgent medical attention or hospitalisation.

If you notice any unwanted effects not mentioned in this leaflet, please inform your doctor, or pharmacist.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using FLOMAXTRA

Storage

Keep FLOMAXTRA tablets in the blister pack until it is time to take them.

Keep your tablets in a cool, dry place where the temperature stays below 25°C.

Do not store FLOMAXTRA in the bathroom or near a sink.

Do not leave them in a car or on a window sill.

Heat and dampness can destroy some medicines.

Keep FLOMAXTRA tablets where children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Note the expiry date on the pack. Do not use after this expiry date.

Disposal

If your doctor tells you to stop taking FLOMAXTRA or the expiry date has passed, ask your pharmacist what to do with any tablets that are left over.

Product Description

The FLOMAXTRA tablet is specially designed to gradually release tamsulosin into the body.

FLOMAXTRA tablets are approximately 9 mm, round, bi-convex, yellow, and engraved with the code '04'.

FLOMAXTRA tablets are supplied in boxes of 10 and 30 tablets.

FLOMAXTRA tablets are sealed in a blister pack.

Ingredients

Active ingredients:

FLOMAXTRA tablets - each tablet contains 400 mcg tamsulosin hydrochloride.

Inactive ingredients:

FLOMAXTRA tablets also contain other inactive ingredients:

- macrogol 7,000,000
- macrogol 8,000
- magnesium stearate
- butylhydroxytoluene
- colloidal silica anhydrous
- hypromellose
- iron oxide yellow.

None of the excipients are derived from animal sources and therefore, where appropriate, FLOMAXTRA tablets are suitable medication for vegetarian, vegan and concerned religious patients.

Further Information

You can obtain more information from your doctor or pharmacist.

Supplier

FLOMAXTRA is supplied in Australia by:

Astellas Pharma Australia Pty Ltd
6 Eden Park Drive
Macquarie Park NSW 2113

Medical Information: 1800 751 755

® = Registered Trademark

Australian registration number:
AUST R 115534

This leaflet was prepared in June 2016.