

# FLOMAXTRA®

Prolonged release tablets

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using FLOMAXTRA®?

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.

For more information, see Section [1. Why am I using FLOMAXTRA®?](#) in the full CMI.

### 2. What should I know before I use FLOMAXTRA®?

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.

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There are a number of circumstances in which a person should not use this medicine or may need to use caution. It is important to understand if these apply to you before taking FLOMAXTRA® (see Section [2. What should I know before I use FLOMAXTRA®?](#) in the full CMI for more details).

### **3. What if I am taking other medicines?**

Some medicines may interfere with FLOMAXTRA® and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I use FLOMAXTRA®?**

The usual dose is one tablet a day. The tablet should be swallowed whole, preferably with a glass of water. Do not crunch, bite or chew the tablet. More instructions can be found in Section [4. How do I use FLOMAXTRA®?](#) in the full CMI.

### **5. What should I know while using FLOMAXTRA®?**

|                             |   |
|-----------------------------|---|
| <b>Things you should do</b> | <ul style="list-style-type: none"><li>• If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking FLOMAXTRA®.</li></ul> |
|-----------------------------|---|

|                                    |   |
|------------------------------------|---|
|                                    | <ul style="list-style-type: none"> <li>● If you are going to have eye surgery for cataracts or glaucoma, please tell your surgeon that you are taking or have taken FLOMAXTRA®.</li> </ul>  |
| <b>Things you should not do</b>    | <ul style="list-style-type: none"> <li>● Do not give FLOMAXTRA® to anyone else, even if they have the same condition as you.</li> <li>● Do not take FLOMAXTRA® for any other complaints unless your doctor tells you to.</li> </ul> |
| <b>Driving or using machines</b>   | <ul style="list-style-type: none"> <li>● Be careful when driving or operating machinery until you know how FLOMAXTRA® affects you. FLOMAXTRA® may cause dizziness and may impair your reactions.</li> </ul>                         |
| <b>Drinking alcohol</b>            | <ul style="list-style-type: none"> <li>● Tell your doctor if you drink alcohol.</li> </ul>  |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"> <li>● Keep FLOMAXTRA® tablets in the blister pack until it is time to take them.</li> </ul>  |

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

For more information, see Section [5. What should I know while using FLOMAXTRA®?](#) in the full CMI.

## 6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). Some serious side effects may include prolonged painful erection of the penis, which is unrelated to sexual activity; swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# FLOMAXTRA®

Prolonged release tablets

**Active ingredient(s):** *tamsulosin (tam-su-lo-sin)*

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## Consumer Medicine Information (CMI)

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 taking this medicine, ask your doctor, nurse or pharmacist.**

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

### Where to find information in this leaflet:

- [1. Why am I using FLOMAXTRA®?](#)
- [2. What should I know before I use FLOMAXTRA®?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use FLOMAXTRA®?](#)
- [5. What should I know while using FLOMAXTRA®?](#)
- [6. Are there any side effects?](#)

### **1. Why am I using FLOMAXTRA®?**

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.**

## **2. What should I know before I use FLOMAXTRA®?**

### **Warnings**

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.

### **Do not use 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.**

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®.

### **Check with your doctor if you:**

- are allergic to FLOMAXTRA® or any of its ingredients (see Section [7. Product Details](#)).

- 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 Section [6. Are there 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®.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### **3. What if I am taking other medicines?**

**Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your 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 Section [6. Are there side effects?](#)).

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

## **4. How do I use 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

## **How to take it**

- 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 you missed.**

## **If you take too much (overdose)**

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should 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.**

## **5. What should I know while using FLOMAXTRA®?**

### **Things you should 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 Section [6. Are there any side effects?](#)).**

## **Things you should 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.**

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how FLOMAXTRA® affects you.**

FLOMAXTRA® may cause dizziness and may impair your reactions.

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

## **Looking after your medicine**

- **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.

## **Getting rid of any unwanted medicine**

**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.**

## **6. Are there any 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.**

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.

## Less serious side effects

| Less serious side effects  | What to do  |
|--|---|
| <ul style="list-style-type: none"><li>● "retrograde ejaculation". When this happens the ejaculation fluid is not squirted out, most of it runs back into the bladder. Retrograde ejaculation is painless.</li><li>● dizziness</li><li>● headache</li><li>● skin rash (red spots or patches), itching, hives</li><li>● weakness</li><li>● dizziness on standing</li><li>● nausea, vomiting, diarrhoea, constipation,</li><li>● fast heart beats</li><li>● blocked nose</li><li>● faintness</li></ul> <p>FLOMAXTRA® can occasionally cause people to feel faint and dizzy.</p> | <p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> |

| <b>Less serious side effects</b>   | <b>What to do</b> |
|--|-------------------|
| <p>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.</p> <p>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,</p> |                   |

| <b>Less serious side effects</b>  | <b>What to do</b> |
|---|-------------------|
| <p data-bbox="199 248 778 405">please tell your surgeon that you are taking or have taken FLOMAXTRA®.</p> <p data-bbox="199 528 778 1032">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.</p> |                   |

### **Serious side effects**

| <b>Serious side effects</b>   | <b>What to do</b>   |
|---|---|
| <ul style="list-style-type: none"> <li data-bbox="199 1435 778 1995">● 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</li> </ul> | <p data-bbox="805 1444 1390 1995"><b>If any of the following happen, tell your doctor or go to accident and emergency at your nearest hospital immediately. These are very serious side effects. If you have them, you may have had a serious allergic reaction</b></p> |

| <b>Serious side effects</b>   | <b>What to do</b>  |
|---|--|
| <p>Room as soon as possible.</p> <ul style="list-style-type: none"> <li>• swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.</li> </ul> | <p><b>to FLOMAXTRA®.</b><br/> <b>You may need urgent medical attention or hospitalisation.</b></p> |

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®.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What FLOMAXTRA® contains

|   |  |
|---|--|
| <b>Active ingredient<br/>(main ingredient)</b>      | FLOMAXTRA® tablets<br>- each tablet contains<br>400 µg tamsulosin<br>hydrochloride.  |
| <b>Other ingredients<br/>(inactive ingredients)</b> | <ul style="list-style-type: none"><li>• macrogol 7,000,000</li><li>• macrogol 8,000</li><li>• magnesium stearate</li><li>• butylhydroxytoluene</li><li>• colloidal silica<br/>anhydrous</li><li>• hypromellose</li><li>• iron oxide yellow.</li></ul> <p>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.</p> |

**Do not take this medicine if you are allergic to any of these ingredients.**

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

## **What FLOMAXTRA® looks like**

FLOMAXTRA® tablets (AUST R 115534) 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.

## **Who distributes FLOMAXTRA®**

FLOMAXTRA® is supplied in Australia by:

Astellas Pharma Australia Pty Ltd

Suite 2.01, 2 Banfield Road

Macquarie Park NSW 2113

Medical Information:

1800 751 755

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