

# FLOMAXTRA(R)

Prolonged release tablet

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## CONSUMER MEDICINE INFORMATION

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### What is in this leaflet

This leaflet contains information about FLOMAXTRA. Please read it carefully before you start to take your medicine. Keep it, as you may want to read it again. The information in this leaflet answers some common questions. Your doctor or pharmacist has more information. This leaflet is not intended to take the place of discussion with your doctor.

Talk to your doctor or pharmacist if there is anything that is worrying you or you do not understand.

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### WHAT IS 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.

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### WHAT IS FLOMAXTRA USED FOR?

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.

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### HOW DOES FLOMAXTRA WORK?

When you pass urine, the urine travels from the bladder through a channel in the prostate. When the prostate gland becomes large, this channel becomes narrow. The channel may even become blocked. If this happens, no urine can be passed. This is a medical emergency.

FLOMAXTRA is a medicine which relaxes smooth muscle, especially in the prostate. In BPH FLOMAXTRA works by widening the channel through the prostate gland. This allows the urine to flow.

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### WHEN SHOULD I NOT TAKE 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.

You should not take FLOMAXTRA if:

- \* you are allergic to any of the ingredients in the tablet (see "WHAT DOES FLOMAXTRA CONTAIN?").
- \* 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).

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## BEFORE YOU TAKE FLOMAXTRA

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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.

Before you start taking FLOMAXTRA tablets you should tell your doctor if you:

- \* are allergic to FLOMAXTRA or any of its ingredients (see "WHAT DOES FLOMAXTRA CONTAIN?").
- \* are taking any other medicines, and what they are. This includes medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. In particular, tell your doctor if you are taking cimetidine, a medicine generally used to treat stomach ulcers or reflux.
- \* 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.

If you are going to have eye surgery for cataracts, please tell your surgeon that you are taking or have taken

FLOMAXTRA. (see "WHAT UNWANTED EFFECTS MAY OCCUR WITH FLOMAXTRA")

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## WHAT UNWANTED EFFECTS MAY OCCUR WITH FLOMAXTRA?

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Most men prescribed FLOMAXTRA benefit. As with any medicines, some side effects may occur.

FLOMAXTRA does not usually cause any problems.

If you develop a skin rash, itchiness or swelling of the face, lips or tongue, tell your doctor immediately, as you may be having an allergic reaction to FLOMAXTRA. Swelling of the face, lips or tongue may cause difficulty in swallowing or breathing.

One side effect of FLOMAXTRA is known as "retrograde ejaculation". When this happens the ejaculation fluid is not squirted out, most of it runs back into the bladder.

Retrograde ejaculation is painless.

Other side effects reported by people taking FLOMAXTRA include dizziness, headache, itching, weakness, dizziness on standing, nausea, vomiting, diarrhoea, constipation, rash, fast heart beats and blocked nose.

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.

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.

If you are having an operation on your eyes because of cataracts 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, please tell your surgeon that you are taking or have taken FLOMAXTRA.

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.

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## HOW MUCH FLOMAXTRA SHOULD I TAKE?

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The dose is one tablet a day. Swallow the tablet whole, preferably with a glass of water. Do not crunch, bite or chew the tablet, as this changes how FLOMAXTRA works.

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 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 have trouble remembering to take FLOMAXTRA, ask your pharmacist for some hints.

## **OVERDOSAGE**

If you think that you or anyone else may have taken too much FLOMAXTRA, contact your doctor or go to the emergency department of your nearest hospital. Do this even if there are no signs of discomfort or poisoning. In New Zealand, call the New Zealand National Poisons Centre on 0800 POISON or 0800 764 766.

Symptoms of overdose may include vomiting, diarrhoea and low blood pressure leading to dizziness or fainting. This is a serious condition and medical attention should be sought immediately.

## **WHAT DOES FLOMAXTRA CONTAIN?**

Each FLOMAXTRA tablet contains 400 micrograms of tamsulosin hydrochloride. 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'.

The FLOMAXTRA tablet also contains macrogol 7,000,000, macrogol 8,000, magnesium stearate, butylhydroxytoluene, colloidal silica anhydrous, hypromellose and 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.

## **HOW TO STORE FLOMAXTRA?**

Keep FLOMAXTRA tablets in the original pack until you use them.

Store FLOMAXTRA tablets below 25 degrees Celsius. Keep the pack in a dry place. Do not store FLOMAXTRA in the bathroom or near the sink, or in a car on a hot day. Do not use after the expiry date on the package. Keep FLOMAXTRA where children cannot reach it.

The Australian Registrational Number is AUST R 115534.

This is not all the information available on FLOMAXTRA. If you have any more questions or are unsure about anything, ask your doctor or pharmacist.

FLOMAXTRA is distributed in Australia by:

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FLOMAXTRA is distributed in New Zealand by:

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and manufactured by:

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