

FLOMAX[®]

relief[®] MR



Read all of this leaflet carefully because it contains important information for you. This medicine is available from your pharmacist without prescription. You will need to see your doctor within 6 weeks of starting treatment, in order to confirm that you can take FLOMAX RELIEF long-term from your pharmacist. You need to take FLOMAX RELIEF as instructed in this leaflet to get the best results from it.

- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice, or you do not understand the instructions
- You must contact your pharmacist or doctor if your symptoms worsen or do not improve after 2 weeks of treatment
- If a side effect occurs and gets troublesome, or seems serious, or if you experience any side effect not listed in this leaflet, tell your doctor or pharmacist

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1. What FLOMAX RELIEF is and what it is used for

The name of your medicine is FLOMAX RELIEF MR. FLOMAX RELIEF is a modified release capsule which contains a medicine called tamsulosin. This belongs to a group of medicines called 'alpha blockers' (or alpha1A-adrenoceptor antagonists).

FLOMAX RELIEF 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)
- Mean 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

FLOMAX RELIEF 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.

2. Before you take FLOMAX RELIEF

FLOMAX RELIEF should be used only by men who are 45 to 75 years of age.

Do not take these capsules if:

- You are allergic (hypersensitive) to tamsulosin or any of the other ingredients of this medicine (listed in Section 6 below)
- You have problems with your heart, liver, or kidneys
- You faint or get dizzy or weak when you sit or stand up suddenly
- You have had your symptoms for less than three months
- You have pain when you urinate, or your urine was cloudy or bloody, at sometime in the last three months
- You have a fever due to an infection of your kidneys or bladder (urinary tract infection)
- You have leaking of your urine which you are unable to control (incontinence)
- You think you have diabetes and it is not properly controlled
- You have had prostate surgery

- You have recently had blurred or cloudy vision and have not been examined by your doctor or optician
- You are about to undergo cataract eye surgery (see Eye surgery below)

Do not take FLOMAX RELIEF if any of the above apply to you, without first consulting your doctor. If you are not sure, talk to your doctor or pharmacist before taking these capsules.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you can buy without a prescription, including herbal medicines.

In particular tell your doctor or pharmacist if you are taking:

- A type of medicine for lowering your blood pressure called an 'alpha blocker' (or alpha₁-adrenoceptor antagonist), such as doxazosin, indoramin, prazosin, terazosin, or verapamil.

Any of these medicines cause lowering of blood pressure and added to FLOMAX RELIEF can result in dizziness and weakness.

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

Driving and using machines

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

Eye surgery

- Do not start taking FLOMAX RELIEF now if you are about to have an operation on your eye for cloudiness of the lens (cataract)
- Please tell your eye specialist if you have ever taken tamsulosin. The operation may need to be performed differently
- If you are currently taking FLOMAX RELIEF, ask your doctor if you should stop taking it for a short time

3. How to take FLOMAX RELIEF

Taking this medicine

- Take one capsule each day
- Take it at the same time each day, after a meal
- Swallow the capsule whole with water
- Do not crush, chew, or open the capsules

Make a note of the date you start taking FLOMAX RELIEF.

After 2 weeks

If you are using FLOMAX RELIEF for the first time and you have not got any better after 2 weeks, or if you get worse, you must stop taking this medicine and ask your pharmacist or doctor for further advice.

Within 6 weeks

You should see your doctor within 6 weeks of starting treatment to confirm that your symptoms are due to BPH.

Every 12 months

You should see your doctor every 12 months to check your prostate. See the doctor sooner if your symptoms change or get worse.

If you forget to take this medicine

- Take your capsule later the same day after food
- If you have missed a dose, just take your daily capsule on the next day at the usual time
- Do not take two capsules to make up for a forgotten capsule

If you take more of this medicine than you should, talk to a doctor or pharmacist straight away.



4. Possible side effects

Like all medicines, FLOMAX RELIEF can cause side effects, although not everybody gets them.

Serious side effects are rare or very rare. Stop taking this medicine and see a doctor straight away if you experience any of the following symptoms - you may need medical treatment:

- Allergic reaction - (affects less than 1 in 1,000 people). The signs may include finding it difficult to breathe, having an itchy rash, having a swollen face, throat, or tongue
- Long-lasting and painful erection (usually not during sexual activity) - affects less than 1 in 10,000 people

The following side effects have also been reported:

Especially when you sit or stand up

- Feeling dizzy (common - affects less than 1 in 10 people)
- Feeling weak (uncommon - affects less than 1 in 100 people)

If this happens, sit or lie down straight away until you feel better.

Uncommon (affects less than 1 in 100 people)

- Headache
- Fast or uneven heart beat (palpitations)
- Runny or blocked nose
- Little or no semen during ejaculation
- Feeling sick or being sick
- Diarrhoea or constipation
- Itching or lumpy rash (urticaria)

Rare (affects less than 1 in 1,000 people)

- Feeling faint

Very rare (affects less than 1 in 10,000 people)

- During an operation on the eye for cloudiness of the lens (cataract), the pupil (the black circle in the middle of your eye) may not increase in size as needed. Also, the iris (the coloured part of the eye) may become floppy during surgery.

Other side effects

As with other medicines of this type, the following side effects may occur:

- Drowsiness
- Blurred vision
- Dry mouth
- Swollen hands or feet

If a side effect occurs and gets troublesome or seems serious, or if you experience any side effect not listed in this leaflet, tell your doctor or pharmacist.

You can also report any side effect you get to the Medicines and Healthcare products Regulatory Agency (MHRA), through the Yellow Card Scheme; you can make a report by filling in a Yellow Card (available from pharmacies), by phoning freephone 0800 100 3352, or on the web at www.yellowcard.gov.uk

Alternatively, you can also report any side effect you get to the marketing authorisation holder Boehringer Ingelheim Limited, Consumer Safety, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, UK, or by phoning free-of-charge on 0800 328 1627.

5. How to store FLOMAX RELIEF

- Keep out of the reach and sight of children
- Do not use the capsules after the expiry date which is stated on the base of the pack
- Do not store above 30°C

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

6. Further information

What FLOMAX RELIEF contains

- The active substance is tamsulosin hydrochloride. Each capsule contains 0.4 mg
- The other ingredients are microcrystalline cellulose, methacrylic acid-ethyl acrylate copolymer, polysorbate, sodium laurilsulfate, triacetin, calcium stearate, and talc. These all help to make the granules which are in the capsule
- The capsule shell contains gelatin, and is coloured with indigotin (E132), titanium dioxide (E171), and yellow and red iron oxide (E172); printing ink is shellac, propylene glycol, and black iron oxide (E172)

What FLOMAX RELIEF looks like and contents of the pack

FLOMAX RELIEF capsules have an orange body and an olive-green cap. The capsules come in packs of 14 and 28 capsules, suitable for 14 and 28 days treatment, respectively.

The marketing authorisation for

FLOMAX RELIEF is held by: Boehringer Ingelheim Limited, Consumer Healthcare, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, UK.

The capsules are manufactured by:

Astellas Pharma Europe B.V., Elisabethhof 19, 2353 EW Leiderdorp, The Netherlands, at their site at Hogemaat 2, 7942 JG Meppel, The Netherlands.

This leaflet was last revised in **September 2009**.

Assessing your symptoms

Your urinary symptoms can be assessed using a questionnaire which you will be asked to complete when you first purchase FLOMAX RELIEF.

To learn more about BPH visit

www.1in4men.com and call the helpline free-of-charge on 0800 731 9070

To request this leaflet free-of-charge in formats such as audio, Braille or large print, please call the Royal National Institute of the Blind (RNIB) freephone on 0800 198 5000. When prompted, please provide the following information:

Product code number 00015/0280

and be ready to confirm the name of this medicine (FLOMAX RELIEF).

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