

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.

1. Why am I using Flosix?

Flosix contains the active ingredient tamsulosin and belongs to a group of medicines called alpha-blockers. Flosix 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. For more information, see Section [1. Why am I using Flosix?](#) in the full CMI.

2. What should I know before I use Flosix?

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

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 Flosix.

Do not use Flosix if you have ever had an allergic reaction to tamsulosin or any of the ingredients listed at the end of the CMI. For more information, see Section [2. What should I know before I use Flosix?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Flosix 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 Flosix?

- 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 Flosix?](#) in the full CMI.

5. What should I know while using Flosix?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Flosix or if you are about to be started on any new medicine. • If you are going to have eye surgery for cataracts or glaucoma, please tell your surgeon that you are taking or have taken Flosix.
Things you should not do	• Do not give Flosix to anyone else, even if they have the same condition as you. • Do not take Flosix for any other complaints unless your doctor tells you to.
Driving or using machines	• Be careful when driving or operating machinery until you know how Flosix affects you. Flosix may cause dizziness and may impair your reactions.
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Keep Flosix tablets in the blister pack until it is time to take them. • Keep your tablets below 25°C.

For more information, see Section [5. What should I know while using Flosix?](#) 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.

Consumer Medicine Information (CMI)

This leaflet provides important information about using Flosix.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Flosix.

Where to find information in this leaflet:

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

1. Why am I using Flosix?

Flosix contains the active ingredient tamsulosin. Flosix belongs to a group of medicines called alpha-blockers. Flosix is a medicine for use by MEN only.

Flosix 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.

Your doctor has prescribed Flosix 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 Flosix has been prescribed for you.

2. What should I know before I use Flosix?

Warnings

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

Do not use Flosix if:

- you are allergic to tamsulosin, or any of the ingredients listed at the end of this leaflet. Always check the

ingredients to make sure you can use this medicine. Signs of an 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 Flosix if the packaging is torn or shows signs of tampering or the tablets do not look quite right.

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

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

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

Your doctor has prescribed Flosix for BPH. Flosix 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 Flosix. 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 Flosix.

Check with your doctor if you:

- are allergic to Flosix 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 Flosix (see Section [6. Are there any side effects?](#)).

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

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 may interfere with Flosix and affect how it works. These medicines include:

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

Taking these medicines with Flosix may increase the risk of possible side effects (See Section [6. Are there any side effects?](#)).

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

4. How do I use Flosix?

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 Flosix 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 Flosix

- Flosix should be swallowed whole, preferably with a glass of water.
- **Do not crunch, bite or chew the tablet, as this changes how Flosix works.**
- Crunching, biting or chewing the tablet will release the medicine quickly and side effects may then occur.

If you forget to take Flosix

Flosix should be used regularly at the same time each day.

- 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 Flosix 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 Flosix (overdose)

If you think that you have used too much Flosix, you may need urgent medical attention.

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.

If you take too many Flosix 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 Flosix?

Things you should do

- Be sure to keep all your doctor's appointments so that your progress can be checked.
- If you are about to be started on a new medicine, tell your doctor and pharmacist that you are taking Flosix.
- 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 Flosix (See Section [6. Are there any side effects?](#)).

Remind any doctor, dentist or pharmacist you visit that you are using Flosix.

Things you should not do

- Do not give Flosix to anyone else, even if they have the same condition as you.
- Do not take Flosix 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 Flosix affects you.

Flosix may cause dizziness and may impair your reactions.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep Flosix tablets in the blister pack until it is time to take them.
- Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place below 25°C away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
General Disorders: - dizziness or faintness 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. - dizziness on standing - weakness - headache - chest discomfort, could be caused or associated with other medical conditions such as respiratory conditions or cardiac disease Skin related: - skin rash (red spots or patches), itching, hives - Flosix may also occasionally cause inflammation and blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals, or nose bleeds. Gut or Gastrointestinal related: - nausea, vomiting, diarrhoea, constipation Heart related: - fast heart beats Eye related: - Flosix may also occasionally cause blurred or reduced vision. - If you are having an operation on your eyes because of cataracts or glaucoma and are already taking or have taken Flosix, 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. Others: "retrograde ejaculation"	Speak to your doctor if you have any of these less serious side effects and they worry you. They are generally mild and do not cause patients to stop taking Flosix. If you are going to have eye surgery for cataracts or glaucoma, please tell your surgeon that you are taking or have taken Flosix.

Less serious side effects	What to do
When this happens, the ejaculation fluid is not squirted out, most of it runs back into the bladder. Retrograde ejaculation is painless. blocked nose	

Serious side effects

Serious side effects	What to do
Allergy Related - swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing. Others - extremely rarely, medications similar to Flosix have caused prolonged painful erection of the penis, which is unrelated to sexual activity.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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. 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 Flosix contains

Active ingredient (main ingredient)	tamsulosin hydrochloride
Other ingredients (inactive ingredients)	Excipients core: - microcrystalline cellulose - hydroxypropyl cellulose - polyethylene oxide - butylated hydroxytoluene - magnesium stearate - silica - colloidal anhydrous. Excipients coating: - hypromellose - hypromellose - macrogol 400 - titanium dioxide - purified talc - quinoline yellow - cochineal - iron oxide black

Potential allergens	This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.
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Do not take this medicine if you are allergic to any of these ingredients.

What Flosix looks like

Flosix 400mcg – brown, round, biconvex modified release tablets with debossing '0.4' on one side and 'SZ' on the other side. (AUST R 336015).

Available in blister packs of 10 and 30 tablets.

Who distributes Flosix

Sponsor

Sandoz Pty Ltd

ABN 60 075 449 553 54

Waterloo Road

Macquarie Park, NSW 2113

Tel: 1800 726 369

Distributor

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30 – 34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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