TAMSULOSIN-WGR SR

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 taking TAMSULOSIN-WGR SR?

TAMSULOSIN-WGR SR contains the active ingredient tamsulosin hydrochloride. TAMSULOSIN-WGR SR is used for the relief of lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH).

For more information, see Section 1. Why am I taking TAMSULOSIN-WGR SR? in the full CMI.

2. What should I know before I take TAMSULOSIN-WGR SR?

Do not use if you have ever had an allergic reaction to TAMSULOSIN-WGR SR or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I take TAMSULOSIN-WGR SR? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TAMSULOSIN-WGR SR 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 take TAMSULOSIN-WGR SR?

- TAMSULOSIN-WGR SR is only to be taken by men.
- The dose is one tablet taken each day.
- Swallow the tablet whole, preferably with a glass of water. Do not crush, bite or chew TAMSULOSIN-WGR SR tablets.

More instructions can be found in Section 4. How do I take TAMSULOSIN-WGR SR? in the full CMI.

5. What should I know while taking TAMSULOSIN-WGR SR?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are taking TAMSULOSIN-WGR SR. Before starting any new medicine, tell your doctor or pharmacist that you are taking TAMSULOSIN-WGR SR. Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. If you are going to have eye surgery for cataracts or glaucoma, tell your surgeon that you are taking or have taking TAMSULOSIN-WGR SR tablets. 	
Things you should not do	 Do not take TAMSULOSIN-WGR SR tablets to treat any other conditions unless your doctor tell you to. Do not give TAMSULOSIN-WGR SR tablets to anyone else, even if they have the same condition as you. Do not take this medicine if you have severe liver disease or severe kidney disease. Do not take TAMSULOSIN-WGR SR if you have a history of orthostatic hypotension (you become dizzy or light-headed or have low blood pressure when you stand up, after sitting or lying down). Do not take this medicine if you are also taking medications which relax the smooth muscle of blood vessels (such as Minipress, Prasig, Hytrin). 	
Driving or using machines	Be careful when driving or operating machinery until you know how TAMSULOSIN-WGR SR affects you. TAMSULOSIN-WGR SR tablets may cause dizziness and may impair your reactions.	
Looking after your medicine	 Keep TAMSULOSIN-WGR SR 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. 	

For more information, see Section 5. What should I know while taking TAMSULOSIN-WGR SR? in the full CMI.

6. Are there any side effects?

Common side effects include: retrograde ejaculation (when ejaculation fluid is not squirted out, but back into the bladder); dizziness.

Serious side effects include: prolonged painful erection of the penis, 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.

TAMSULOSIN-WGR SR

Active ingredient: tamsulosin hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about taking TAMSULOSIN-WGR SR. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking TAMSULOSIN-WGR SR.

Where to find information in this leaflet:

- 1. Why am I taking TAMSULOSIN-WGR SR?
- 2. What should I know before I take TAMSULOSIN-WGR SR?
- 3. What if I am taking other medicines?
- 4. How do I take TAMSULOSIN-WGR SR?
- 5. What should I know while taking TAMSULOSIN-WGR SR?
- 6. Are there any side effects?
- 7. Product details

1. Why am I taking TAMSULOSIN-WGR SR?

TAMSULOSIN-WGR SR contains the active ingredient tamsulosin hydrochloride. Tamsulosin hydrochloride belongs to a group of medicines called alpha-blockers.

TAMSULOSIN-WGR SR is for use by MEN only. TAMSULOSIN-WGR SR is used in men who have a medical condition called benign prostatic hyperplasia (also known as BPH). The prostate gland is at the outlet of the urinary bladder. In BPH, the prostate gland is bigger than normal, which may affect how well you are able to pass your urine. BPH is common in men over the age of 50 years and is NOT prostate cancer.

TAMSULOSIN-WGR SR is used to treat the symptoms of benign prostatic hyperplasia, including:

- a slow urine flow, the urine stream may become a trickle, or it may stop and start.
- a delay when you try to pass urine, or straining to do so.
- · inability to empty your bladder completely.
- dribbling at the end of passing urine.
- the need to pass urine often during the day.
- the need to get up often during the night to pass urine.
- a feeling of urgency to pass urine as soon as you first feel the need to do so.

2. What should I know before I take TAMSULOSIN-WGR SR?

Warnings

Do not take TAMSULOSIN-WGR SR if:

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

Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

- you are a woman or a child. TAMSULOSIN-WGR SR is for use by MEN only. If you are not sure whether you should start taking TAMSULOSIN-WGR SR you should contact your doctor.
- you have a history of orthostatic hypotension (where you become dizzy or light-headed or have low blood pressure when you stand up, after sitting or lying down).
- you have severe kidney disease.
- you have severe liver disease.
- you are taking other medication which relaxes the smooth muscle of blood vessels (some of the tradenames are Minipress, Prasig, Hytrin).

Do not take TAMSULOSIN-WGR SR if the expiry date (Exp.) printed on the pack has passed.

Do not take TAMSULOSIN-WGR SR if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have prostate cancer. TAMSULOSIN-WGR SR 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 taking TAMSULOSIN-WGR SR.
 - It is recommended that men be checked for prostate cancer once a year, from 50 years of age onwards.
- have allergies to a any other medicines, or any other substances, such as foods, preservatives or dyes, particularly to sulfa.
- 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.
- you plan to have surgery, particularly eye surgery for cataracts or glaucoma. Your doctor will discuss the risks and benefits of using TAMSULOSIN-WGR SR.
- have any other medical conditions.

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 <u>6</u>. 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 TAMSULOSIN-WGR SR and affect how it works. These include:

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TAMSULOSIN-WGR SR.

Do not take TAMSULOSIN-WGR SR if you are taking other medication which relaxes the smooth muscle of blood vessels (some of the TAMSULOSIN-WGR SRs are Minipress, Prasig, Hytrin).

4. How do I take TAMSULOSIN-WGR SR?

How much to take

- The dose is one tablet taken each day.
- Patients with severe liver problems should not take these tablets.
- Patients with severe kidney problems should not take these tablets.
- Follow all directions given to you by your doctor and pharmacist carefully.

How to take TAMSULOSIN-WGR SR

- Swallow the tablets whole, preferably with a glass of water
- Do not crush, bite or chew the tablet, as this changes how TAMSULOSIN-WGR SR tablets work.
- TAMSULOSIN-WGR SR should be used regularly at the same time each day.

If you forget to take TAMSULOSIN-WGR SR

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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

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

If you are not sure what to do, ask your doctor or pharmacist.

If you use too much TAMSULOSIN-WGR SR

If you think that you have used too much TAMSULOSIN SR-WGR, 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 TAMSULOSIN-WGR SR 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 taking TAMSULOSIN-WGR SR?

Things you should do

Before starting any new medicine, tell your doctor or pharmacist that you are taking TAMSULOSIN-WGR SR tablets.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking TAMSULOSIN-WGR SR tablets.

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 TAMSULOSIN-WGR SR tablets.

Things you should not do

Do not use TAMSULOSIN-WGR SR tablets to treat any other conditions unless your doctor tell you to.

Do not give TAMSULOSIN-WGR SR tablets to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TAMSULOSIN-WGR SR affects you.

TAMSULOSIN-WGR SR may cause dizziness or impair your reactions.

Looking after your medicine

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

Keep your tablets below 25°C.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place 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.

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

Les	s serious side effects	What to do
Cor	mmon: "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	Speak to your doctor if you have any of these less serious side effects and they worry you.
Un	headache skin rash (red spots or patches), itching, hives weakness dizziness on standing nausea, vomiting, diarrhoea, constipation fast heart beats blocked nose burred or changes to vision inflammation and blistering of the skin or mucous membranes of the lips, eyes, mouth, nasal passages or genitals, or nose bleeds.	
Rare: • faintness		

TAMSULOSIN-WGR SR 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 lightheadedness. 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 TAMSULOSIN-WGR SR, 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 TAMSULOSIN SR-WGR.

TAMSULOSIN-WGR SR 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.

Serious side effects

Serious side effects	What to do
 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. 	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.

Each TAMSULOSIN-WGR SR tablet contains 400 micrograms of tamsulosin hydrochloride.

What TAMSULOSIN-WGR SR contains

Active ingredient (main ingredient)	tamsulosin hydrochloride
Other ingredients (inactive ingredients)	microcrystalline cellulose polyethylene oxide magnesium stearate

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

The tablets do not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

What TAMSULOSIN-WGR SR looks like

TAMSULOSIN-WGR SR tablets are white to off-white round tablets with a diameter of approximately 9 mm, debossed with "TSLN" on one side and "0.4" on the other side.

Each pack contains 30 tablets. (AUST R 433930).

Who distributes TAMSULOSIN-WGR SR

Wagner Pharmaceuticals Pty Ltd 6 Albert Street Preston, Victoria, 3072

Tel: 1800 936 140

This leaflet was prepared in May 2024.