

Xatral® 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 using Xatral SR?

Xatral SR contains the active ingredient alfuzosin hydrochloride. Xatral SR is used to a medical condition in men called Benign Prostatic Hyperplasia or BPH. For more information, see Section [1. Why am I using Xatral SR?](#) in the full CMI.

2. What should I know before I use Xatral SR?

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

Do not use if you have liver disease; you are currently taking another alpha-blocker: prazosin (Minipress), doxazosin and tamsulosin (Flomaxtra); you are currently taking potent CYP3A4 inhibitors (medicines used to treat certain types of infections): ketoconazole (Nizoral), itraconazole (Sporanox) and ritonavir (Norvir); you have

a history of feeling dizzy, tired or sweating on standing (orthostatic hypotension).

Talk to your doctor if you have any other medical conditions or take any other medicines.

For more information, see Section [2. What should I know before I use Xatral SR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Xatral 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 use Xatral SR?

- The standard dose for this medicine is one tablet taken after a meal once each day, swallowed whole with a glass of water.
- Do not divide, crush or chew the tablets.

More instructions can be found in Section [4. How do I use Xatral SR?](#) in the full CMI.

5. What should I know while using Xatral SR?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using Xatral SR.

	<ul style="list-style-type: none"> • If you are having any kind of surgery, tell your doctor you are using Xatral SR.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly or lower the dosage, without checking with your doctor or pharmacist.
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how Xatral SR affects you.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol. • Xatral SR could increase the effects of alcohol. Avoid drinking alcohol while taking it.
Looking after your medicine	<ul style="list-style-type: none"> • Store it in a cool dry place below 25°C away from moisture, heat or sunlight.

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

6. Are there any side effects?

Common side effects may include faintness or dizziness; headaches; sweating or flushes; nausea or vomiting; stomach pain or diarrhoea; dry mouth; tiredness, drowsiness or weakness; inflammation or irritation of the nose; oedema (swelling). Serious side effects may include: irregular heart beat or palpitations; chest pain; yellowing of the skin or eyes; hives or severe skin reactions; bleeding or bruising more easily than normal. Very serious side effects may include: allergy symptoms. 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.

Xatral[®] SR (zar-trel)

Active ingredient: *Alfuzosin* (al-few-zo-sin)
hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Xatral 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 using Xatral SR.**

Where to find information in this leaflet:

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

1. Why am I using Xatral SR?

Xatral SR contains the active ingredient alfuzosin hydrochloride. It belongs to a group of medicines called alpha1-receptor blockers.

Xatral SR is used to treat a medical condition in men called Benign Prostatic Hyperplasia or BPH.

BPH is a condition where the prostate gland (which is near your bladder) has become bigger making it more difficult for you to pass urine. This can lead to symptoms such as:

- Weak or interrupted stream of urine
- Feeling that you cannot empty your bladder completely
- Delay before you start to pass urine
- Needing to pass urine often, especially at night
- Feeling that you must pass urine right away

Xatral SR works by relaxing the muscles in the prostate gland and increasing the flow of urine.

2. What should I know before I use Xatral SR?

Warnings

Do not use Xatral SR if:

- you are allergic to alfuzosin, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have liver disease.
- you are currently taking another alpha-blocker.
 - These include prazosin (Minipress), doxazosin and tamsulosin (Flomaxtra).

- you are currently taking potent CYP3A4 inhibitors (medicines used to treat certain types of infections)
 - These include ketoconazole (Nizoral), itraconazole (Sporanox) and ritonavir (Norvir)
- you have a history of feeling dizzy, tired or sweating on standing (orthostatic hypotension).

Check with your doctor if you:

- have allergies to:
 - any other alpha-blockers, including prazosin (Minipress), doxazosin and tamsulosin (Flomaxtra)
 - any other substances, such as foods, preservatives or dyes.
- have any other medical conditions, especially:
 - angina (a feeling of pain, tightness, heaviness or pressure in the chest)
 - Parkinson's disease
 - multiple sclerosis
 - heart failure
 - prostate cancer
 - high blood pressure
 - heart conditions or heart problems
- take any medicines for any other condition

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?](#)

Use in people other than adult men

Xatral SR is not intended for use in women.

Do not give Xatral SR to a child or adolescent. There is no experience with its use in children or adolescents under 18 years old.

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 Xatral SR and affect how it works. These include:

- medicines to lower blood pressure
- other alpha-blockers, including prazosin (Minipress), doxazosin and tamsulosin (Flomaxtra)
- non-selective alpha-blockers, including labetalol (Trandate) and phenoxybenzamine (Dibenyline)
- nitrates (medicines which aid the dilation of constricted blood vessels)
- potent CYP3A4 inhibitors (medicines used to treat certain types of infections) such as ketoconazole (Nizoral), itraconazole (Sporanox) and ritonavir (Norvir)
- general anaesthetics (medicines used to put you to sleep during an operation or procedure)

- medicines used to treat a fast or irregular heart beat e.g. amiodarone, quinidine, disopyramide.

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

4. How do I use Xatral SR?

How much to take

- The standard dose for this medicine is one tablet taken once each day.
- Your doctor may have prescribed a different dose.
- Follow the instructions provided and use Xatral SR until your doctor tells you to stop.

When to take / use Xatral SR

- Take Xatral SR after a meal, at about the same time each day.

Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.

How to take Xatral SR

- Swallow the tablets whole with a full glass of water.

Do not divide, crush or chew the tablets. If they are broken or crushed they will not work over 24 hours as they are supposed to and it may increase the risk of side effects.

If you forget to use Xatral SR

Xatral SR should be used regularly at the same time each day.

If it is almost time for your next dose (within 12 hours), skip the dose you missed and take your next dose when you are meant to.

Otherwise, it as soon as you remember, and then go back to taking it as you would normally.

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

If you use too much Xatral SR

If you take too much Xatral SR, you may feel light-headed, dizzy, tired, drowsy or sweaty.

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

You should immediately:

- phone the Poisons Information Centre (**by calling Australia 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.

5. What should I know while using Xatral SR?

Things you should do

- If you are undergoing eye surgery because of cataract (cloudiness of the lens) please inform your eye specialist before the operation that you are using or have previously used Xatral SR.

This is because Xatral SR may cause complications during the surgery which can be managed if your specialist is prepared in advance.

- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

In most cases, Xatral SR will need to be stopped before surgery.

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

Things you should not do

- Do not stop using this medicine suddenly; if you need to stop taking Xatral SR your doctor will slowly reduce the dose over a number of days or weeks
- Do not lower the dosage, without checking with your doctor or pharmacist.
- Do not divide, crush or chew the tablets.

- Do not take more than the recommended dose unless your doctor or pharmacist tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Things to be careful of

Xatral SR may cause dizziness, light-headedness and fainting, especially if you get up too quickly. This is also more likely to occur if you have just started Xatral SR or the dose has just been increased. Therefore:

- get up slowly after you have been sitting or lying down
- if you feel dizzy or light-headed, lie down so that you do not faint. Then sit up for a few moments before standing to prevent the dizziness from returning

If the symptoms continue, tell your doctor or pharmacist

Driving or using machines

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

Xatral SR may cause light-headedness, tiredness or weakness in some people, especially after the first dose or after a dose increase.

Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy.

Drinking alcohol

Tell your doctor if you drink alcohol.

The effects of alcohol (dizziness or light-headedness) could be made worse while taking Xatral SR. It is recommended that you do not drink alcohol while taking it.

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them.
- If you take the tablets out of the blister pack they may not keep well.

Follow the instructions on 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.

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
<p>Nervous system-related:</p> <ul style="list-style-type: none">• faintness or dizziness• headaches• tiredness, drowsiness or weakness. <p>Gut-related:</p> <ul style="list-style-type: none">• nausea or vomiting• stomach pain or diarrhoea• dry mouth. <p>Other:</p> <ul style="list-style-type: none">• sweating or flushes• inflammation or irritation of the nose	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • oedema (swelling). 	

Serious side effects

Serious side effects	What to do
<p>Heart related:</p> <ul style="list-style-type: none"> • irregular heart beat or palpitations • chest pain <p>Skin and eye related:</p> <ul style="list-style-type: none"> • yellowing of the skin or eyes • hives or severe skin reactions. <p>Blood related:</p> <ul style="list-style-type: none"> • bleeding or bruising more easily than normal 	<p>Call your doctor straight away, if you notice any of these serious side effects.</p>

Very serious side effects

Very serious side effects	What to do
<p>Allergic reaction-related:</p> <ul style="list-style-type: none"> • swelling of the face, lips, mouth or throat, which 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</p>

Very serious side effects	What to do
may cause difficulty in swallowing or breathing.	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 Xatral SR contains

Active ingredient (main ingredient)	alfuzosin hydrochloride (10 mg)
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<p>Other ingredients (inactive ingredients)</p>	<p>ethylcellulose hydrogenated castor oil hypromellose yellow iron oxide magnesium stearate microcrystalline cellulose povidone silicon dioxide mannitol.</p>
<p>Potential allergens</p>	<p>Xatral SR does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.</p>

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

What Xatral SR looks like

Xatral SR is three layered biconvex tablets: two of the layers are yellow with a white layer in-between. It is a sustained release preparation.

A blister pack contains 30 tablets.

(Aust R 81900).

Who distributes Xatral SR

Distributed by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

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