

Xatral(R) SR

(zar-trel)

Alfuzosin (al-few-zo-sin)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Xatral SR tablets.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Xatral is used for

Xatral belongs to a group of medicines called alpha1-receptor blockers.

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

Your doctor, however, may prescribe Xatral for another purpose.

Ask your doctor or pharmacist if you have any questions about why it has been prescribed for you.

This medicine is only available with a doctor's prescription.

There is no evidence that this medicine is addictive.

Before you take it

When you must not take it

Do not take Xatral if you have liver disease.

Do not take Xatral if you are currently taking another alpha-blocker.

These include prazosin (Minipress), terazosin (Hytrin) and tamsulosin (Flomaxtra).

Do not take Xatral if you have a history of feeling dizzy, tired or sweating on standing (orthostatic hypotension).

Do not take Xatral if you are allergic to it or any of the ingredients listed at the end of this leaflet.

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

Xatral is not intended for use in women.

Do not give Xatral to a child or adolescent.

There is no experience with its use in children or adolescents under 18 years old.

Do not take it after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is damaged or shows signs of tampering.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- * any of the ingredients listed at the end of this leaflet
- * any other alpha-blockers, including prazosin (Minipress), terazosin (Hytrin) and tamsulosin (Flomaxtra)
- * any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- * angina (a feeling of pain, tightness, heaviness or pressure in the chest)
- * Parkinson's disease

- * multiple sclerosis
- * heart failure
- * prostate cancer
- * high blood pressure.

Tell your doctor or pharmacist if you plan to have surgery.

If you have not told your doctor or pharmacist about any of the above, tell them before you take Xatral.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Xatral and some other medications may interfere with each other. These include:

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

These medicines may be affected by Xatral, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines. Your doctor or pharmacist will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Xatral.

How to take it

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.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how many to take.

Follow the instructions they give you.

If you take the wrong dose, Xatral may not work as well and your problem may not improve.

How to take it

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.

When to take it

Take Xatral 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.

If you are not sure when to take it, ask your doctor or pharmacist.

How long to take it

Continue taking your medicine for as long as your doctor or pharmacist tells you.

Do not stop taking the tablets suddenly or allow your tablets to run out.

If you need to stop taking Xatral your doctor will slowly reduce the dose over a number of days or weeks.

Ask your doctor or pharmacist if you are not sure how long to take the medicine for.

If you forget to take it

Do not try to make up for missed doses by taking more than one dose at a time.

This may increase the chance of getting an unwanted side effect.

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

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

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

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

If you have trouble remembering when to take your medicine, ask your pharmacist for hints.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Xatral.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are taking it

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Xatral.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Xatral.

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.

This is because Xatral 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 will need to be stopped before surgery.

Things you must not do

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.

Do not stop taking Xatral, or lower the dosage, without checking with your doctor or pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how Xatral affects you.

It may cause dizziness, 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.

It is recommended that you do not drink alcohol while taking Xatral.

The effects of alcohol (dizziness or light-headedness) could be made worse while taking Xatral.

Get up slowly after you have been sitting or lying down.

Xatral 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 or the dose has just been increased.

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.

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Xatral.

It helps most people with BPH, but it may have unwanted side effects in a few people.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- * 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).

These are mild side effects of this medicine and are usually short-lived.

Tell your doctor or pharmacist immediately if you notice any of the following:

- * irregular heart beat or palpitations
- * chest pain
- * yellowing of the skin or eyes
- * hives or severe skin reactions.

These may be serious side effects of Xatral. You may need urgent medical attention. Serious side effects are uncommon.

If any of the following happen, stop taking this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- * swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Xatral. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

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

Other side effects not listed above may occur in some consumers.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

After taking it

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

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.

Keep the medicine in a cool, dry place where the temperature stays below 25 degrees C.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor or pharmacist tells you to stop taking Xatral, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

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

Xatral is a sustained release preparation.

A blister pack contains 30 or 60 tablets.

Ingredients

Active Ingredient:

Alfuzosin hydrochloride 10mg

Inactive Ingredients:

- * ethylcellulose
- * hydrogenated castor oil
- * hypromellose
- * yellow iron oxide
- * magnesium stearate
- * microcrystalline cellulose
- * povidone
- * silica colloidal hydrated
- * mannitol.

Xatral does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

Manufacturer/Sponsor

Xatral is made in France.

Xatral is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

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