

TOPROL-XL™

23.75, 47.5, 95, 190 TABLETS

Metoprolol succinate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about TOPROL-XL TABLETS. It does not contain all the information that is known about TOPROL-XL.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking TOPROL-XL 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 TOPROL-XL is for

TOPROL-XL belongs to a group of medicines called beta-blockers.

It works by affecting the body's response to some nerve impulses, especially in the heart. As a result, it decreases the heart's need for blood and oxygen and therefore reduces the amount of work the heart has to do. It also helps the heart to beat more regularly.

TOPROL-XL tablets are used to treat heart failure - increase survival, reduce hospitalisation and improve symptoms. It is used in combination with other medicines to treat your condition.

Your doctor may have prescribed this medicine for another reason.

Your doctor will have explained why you are being treated with TOPROL-XL and told you what dose to take.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Ask your doctor if you have any questions about why TOPROL-XL has been prescribed for you.

TOPROL-XL is not addictive.

Before you take TOPROL-XL

When you must not take it

Do not take TOPROL-XL tablets if:

- 1. you have or have had asthma (difficulty in breathing, wheezing and coughing), bronchitis or other lung problems in the past.**
- 2. you have the following conditions:**
 - a history of allergic problems, including hayfever
 - a very slow heart beat
 - a severe blood vessel disorder causing poor circulation in the arms and legs
 - certain other heart conditions
 - phaeochromocytoma (a rare tumour of the adrenal gland) which is not being treated with other medicines
 - low blood pressure (hypotension)
- 3. you are pregnant or intend to become pregnant**

TOPROL-XL may affect your baby if you are given it early in pregnancy or in the last weeks before your baby is due.

- 4. you are breast-feeding or plan to breast-feed**

TOPROL-XL passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

Do not use TOPROL-XL if the expiry date (EXP) printed on the pack has passed.

It may have no effect at all, or worse, an entirely unexpected effect if it is used after the expiry date.

Do not use TOPROL-XL if the packaging is torn or shows signs of tampering.

Do not give TOPROL-XL to children.

The safety and effectiveness of TOPROL-XL in children has not been established.

Before you start to take it

You must tell your doctor if:

1. you have any allergies to

- TOPROL-XL or any of the ingredients listed at the end of this leaflet
- any other medicine or other beta-blocker medicines
- any other substances, such as foods, preservatives or dyes

2. you have any of these medical conditions

- asthma or other lung problems, even if you have had them in the past
- allergic problems, including hayfever

- diabetes
- very slow heart beat (less than 45-50 beats/minute)
- severe blood vessel disorder causing poor circulation in the arms and legs
- liver problems
- kidney problems
- certain types of angina
- any other heart problems
- pheochromocytoma
- hyperthyroidism (an overactive thyroid gland)

Tell you doctor if you plan to have surgery.

If you have not told your doctor about any of these things, tell them before you take TOPROL-XL.

Taking other medicines

Tell your doctor if you are taking any other medicines, including

- other beta-blocker medicines, including beta-blocker eye drops
- medicines used to treat high blood pressure or angina

- medicines used to treat heart problems
- insulin and tablets used to treat diabetes
- medicines used to treat bacterial infections (e.g. rifampicin, quinidine)
- anti-ulcer drugs (e.g. cimetidine)
- anti-inflammatory drugs
- medicines used to treat depression
- warfarin
- monoamine-oxidase inhibitors (MAOIs)
- medicines that you buy without a prescription at the chemist, supermarket or health food shop

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking TOPROL-XL.

If you have not told your doctor about any of these things, tell them before you take any TOPROL-XL.

Taking TOPROL-XL

How much to take

The usual starting dose is half a 23.75 mg or a whole 23.75 mg tablet once a day for one to two weeks. The dose is then usually doubled every second week up to a maximum dose of 190 mg once daily or to the highest tolerated dose.

TOPROL-XL tablets may be broken in half or swallowed whole with a glass of water as directed by your doctor. TOPROL-XL tablets should not be chewed or crushed.

Your doctor may tell you to take a different amount of TOPROL-XL.

Follow your doctor's instructions carefully.

If you are taking other medicines your doctor may need to change the dose of them to obtain the best results for you.

DO NOT STOP TAKING TOPROL-XL TABLETS SUDDENLY.

The dose needs to be reduced slowly over at least 14 days to make sure your condition does not get worse. Your doctor will tell you how to reduce the dose.

If you forget to take it

If you miss a dose of TOPROL-XL and your next dose is more than 12 hours away, take the missed dose right away.

If your next dose is less than 12 hours away take only half the dose.

Take your next dose when you are meant to.

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

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

Overdose

Telephone your doctor, the Poisons Information Centre (13 11 26) or go to casualty at your nearest hospital immediately if you think that you or anyone else may have taken too much TOPROL-XL. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too many TOPROL-XL tablets your blood pressure may drop too far. You will feel faint or may faint, and your heart rate will also slow down. You may also have nausea, vomiting and shortness of breath. In extreme cases, serious heart and lung problems may occur.

While you are using TOPROL-XL

Things you must do

Be sure to keep all of your doctor's appointments so that your progress can be checked.

If you become pregnant while taking TOPROL-XL, tell your doctor.

If you have a severe allergic reaction to foods, medicines or insect stings, tell your doctor immediately.

If you have a history of allergies, there is a chance that TOPROL-XL may cause allergic reactions to be worse and harder to treat.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

You may feel light-headed or dizzy when you begin to take TOPROL-XL. This is because your blood pressure has fallen suddenly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem gets worse or continues, talk to your doctor.

If you feel a worsening of your condition in the early stages of taking TOPROL-XL

Some people may experience an apparent worsening of their condition in the early stages of treatment with TOPROL-XL. It is important to tell your doctor if this happens to you, although it is usually temporary. If your condition continues to worsen, you should see your doctor as soon as possible.

Make sure you drink enough water during exercise and hot weather when you are taking TOPROL-XL, especially if you sweat a lot.

If you do not drink enough water while taking TOPROL-XL, you may feel faint or light-headed or sick. This is because your blood pressure is dropping too much. If you continue to feel unwell, tell your doctor.

If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking TOPROL-XL.

Your blood pressure may drop suddenly if TOPROL-XL interacts with the anaesthetic.

If you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor.

TOPROL-XL may change how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar (hypoglycaemia). TOPROL-XL may increase the time your body takes to recover from low blood sugar. Your doses of diabetic medicines, including insulin, may need to change.

If you have to have any medical tests while you are taking TOPROL-XL, tell your doctor.

TOPROL-XL may affect the results of some tests.

Tell any doctors, dentists, and pharmacists who are treating you that you are taking TOPROL-XL.

Things you must not do

Do not stop taking TOPROL-XL without checking with your doctor.

Your doctor may want you to gradually reduce the amount of TOPROL-XL you are taking before stopping completely. This may help reduce the possibility of your condition worsening or other heart complications occurring.

Do not give TOPROL-XL to anyone else even if they have the same condition as you.

Do not use TOPROL-XL to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how TOPROL-XL affects you.

As with other beta-blocker medicines, TOPROL-XL may cause dizziness, light-headedness, tiredness, or drowsiness in some people. Make sure you know how you react to TOPROL-XL before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

Be careful drinking alcohol while you are taking TOPROL-XL.

If you feel dizzy or lightheaded when you take TOPROL-XL, these conditions may get worse when you drink alcohol.

Dress warmly during cold weather, especially if you will be outside for a long time (for example when playing winter sports).

TOPROL-XL, like other beta-blocker medicines, tend to decrease blood circulation in the skin, fingers and toes. It may make you more sensitive to cold weather, especially if you have circulation problems.

Side effects

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

If you get any side effects, do not stop taking TOPROL-XL without first talking to your doctor.

TOPROL-XL helps most people with heart failure, but it may have unwanted side-effects in a few people.

If you are over 65 years of age you may have an increased chance of getting side effects.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

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

- headache, tiredness, drowsiness, weakness, or lack of energy
- aches and pains, painful joints
- nausea (feeling sick), vomiting,
- stomach upset, diarrhoea or constipation, weight gain
- dry mouth, changes in taste sensation
- difficulty sleeping, nightmares
- mood changes
- confusion, short-term memory loss, inability to concentrate
- increased sweating, runny or blocked nose
- hair loss

These side effects are usually mild.

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

- dizziness, light headedness or fainting especially on standing up
- tingling or "pins and needles"

- skin rash or worsening of psoriasis
- sunburn happening more quickly than usual
- abnormal thinking or hallucinations
- buzzing or ringing in the ears, deafness
- irritated eyes or blurred vision
- sexual problems

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor or nurse immediately:

- shortness of breath, being less able to exercise
- swelling of the ankles, feet or legs
- chest tightness, wheezing, noisy breathing
- chest pain, changes in heart rate or palpitations
- swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing, which may be signs of a serious allergic reaction
- yellowing of the skin or eyes (jaundice), generally feeling unwell

- constant "flu-like" symptoms with tiredness or lack of energy

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Some people may get other side effects while being given TOPROL-XL.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using TOPROL-XL

Storage

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

If you take TOPROL-XL out of the blister pack it will not keep well.

Keep the tablets in a cool dry place where the temperature stays below 30 degrees C.

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

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

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.

Disposal

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Product description

What TOPROL-XL looks like

TOPROL-XL 23.75 tablets are white to off-white, oval, scored on both sides and marked A/Beta Symbol on one side.

TOPROL-XL 47.5 tablets are white to off-white, round, scored on one side and marked A/mO on the other side.

TOPROL-XL 95 tablets are white to off-white, round, scored on one side and marked A/mS on the other side.

TOPROL-XL 190 tablets are white to off-white, oval, scored on one side and marked A/mY on the same side.

Ingredients

Each TOPROL-XL tablet contains the active ingredient:

Metoprolol succinate 23.75, 47.5, 95 or 190 mg, and the excipients:

Ethylcellulose

Hydroxypropylcellulose

Hypromellose

Microcrystalline cellulose

Paraffin - synthetic

Macrogol 6000

Silicon dioxide

Sodium stearyl fumarate

Titanium dioxide

Manufacturer

AstraZeneca Pty Ltd

ABN 54 009 682 311

Alma Road

NORTH RYDE NSW 2113

Australian Registration Number:

TOPROL-XL™ 23.75

Blister pack of 15 tablets

AUST R 97785

TOPROL-XL™ 47.5

Blister pack of 30 tablets

AUST R 97786

TOPROL-XL™ 95

Blister packs of 30 tablets

AUST R 97787

TOPROL-XL™ 190

Blister pack of 30 tablets

AUST R 97788

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