

NEW ZEALAND CONSUMER MEDICINE INFORMATION

Topreloc-XL

**Metoprolol succinate Modified Release Tablet Blister/Bottle Pack
23.75 mg, 47.5 mg, 95 mg and 190 mg**

What is in this leaflet

Please read this leaflet carefully before you start taking Topreloc-XL.

This leaflet answers some common questions about Topreloc-XL.

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 has weighed the risks of you taking Topreloc-XL against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.
You may need to read it again.

What Topreloc-XL is used for

Topreloc-XL contains the active ingredient metoprolol succinate.

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

Topreloc-XL tablets are used to treat heart failure. It is used in combination with other medicines to treat your condition.

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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Topreloc-XL is not addictive.

- You have a very slow heartbeat (less than 45-50 beats/minute)
- You have a certain other heart conditions
- You have phaeochromocytoma (a rare tumour of the adrenal gland) which is not being treated already with other medicines
- you have a severe blood vessel disorder causing poor circulation in the arms and legs
- you are receiving/having emergency treatment for shock or severely low blood pressure.

If you are not sure whether any of the above medical conditions apply to you, check with your doctor.

Do not take Topreloc-XL after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not give Topreloc-XL to children.

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

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it:

Tell your doctor if you are allergic to:

- metoprolol succinate or any of the ingredients listed at the end of this leaflet
- any other medicine including other beta-blocker medicines
- any other substances, such as

Before you take

Topreloc-XL

When you must not take it:

Do not take Topreloc-XL if you have an allergy to:

- you are allergic to any medicine containing metoprolol succinate or any of the ingredients listed at the end of this leaflet or any other beta-blocker medicine.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin or you may feel faint.

- you have or have had asthma, difficulty in breathing, wheezing, bronchitis or other lung problems in the past
- You have a history of allergic problems including hayfever
- You have a low blood pressure

foods, preservatives or dyes

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

- 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
- phaeochromocytoma, a rare tumour of the adrenal gland
- hyperthyroidism (an overactive thyroid gland)

Tell your doctor if you are pregnant or plan to become pregnant

- Like most beta-blocker medicines, Topreloc-XL is not recommended for use during pregnancy.

Tell your doctor if you are breastfeeding or plan to breastfeed.

- The active ingredient in Topreloc-XL passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Topreloc-XL

Taking other medicines

Tell your doctor or pharmacist if

Topreloc-XL CMI

you are taking any other medicines, including any that you get without prescription from your pharmacy, supermarket or health food shop.

Some medicines and Topreloc-XL may interfere with each other. These include:

- other beta-blocker medicines, including beta-blocker eye drops
- calcium channel blockers or calcium antagonists, medicines used to treat high blood pressure and angina, for example verapamil and diltiazem
- medicines used to treat high blood pressure, for example clonidine, hydralazine, and prazosin
- medicines used to treat abnormal or irregular heartbeat, for example amiodarone, disopyramide and quinidine
- medicines used to treat arthritis, pain, or inflammation, for example indomethacin and ibuprofen
- digoxin, a medicine used to treat heart failure
- medicines used to treat diabetes
- medicines used to treat bacterial infections, for example rifampicin
- cimetidine, a medicine used to treat stomach ulcers
- medicines used to treat depression
- warfarin, a medicine used to prevent blood clots
- monoamine-oxidase inhibitors (MAOIs)

These medicines may be affected by Topreloc-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.

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

How to take Topreloc-XL

Take Topreloc-XL exactly as your doctor has prescribed.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

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.

How to take it

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

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

How long to take it

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

This medicine helps to control your condition, but does not cure it.

It is important to keep taking your medicine even if you feel well.

DO NOT STOP TAKING Topreloc-xl TABLETS SUDDENLY.

The dose needs to be reduced slowly over 7 to 14 days to make sure that your condition does not get worse.

Your doctor will tell you how to gradually reduce the dose before stopping completely.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and 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 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 some hints.

While you are taking Topreloc-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 Topreloc-xl, tell your doctor immediately.

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 Topreloc-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 Topreloc-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 Topreloc-xl, tell your doctor immediately.

Some people may experience an apparent worsening of their condition in the early stages of treatment with Topreloc-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 Topreloc-xl, especially if you sweat a lot.

If you do not drink enough water while taking Topreloc-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 are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor.

Topreloc-xl may change how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar (hypoglycaemia). Topreloc-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 are about to be started on

any new medicine, remind your doctor and pharmacist that you are taking Topreloc-xl.

Tell any doctors, dentists, and pharmacists who are treating you that you are taking Topreloc-xl.

If you plan to have surgery (even at the dentist) that needs an anaesthetic, tell your doctor or dentist that you are taking Topreloc-xl.

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

Topreloc-xl may affect the results of some tests.

Things you must not do

Do not stop taking Topreloc-xl without checking with your doctor.

Your doctor may want you to gradually reduce the amount of Topreloc-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 Topreloc-xl to anyone else even if they have the same condition as you.

Do not use Topreloc-xl to treat any other complaints unless your doctor tells you to.

Things to be careful of

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Topreloc-xl affects you.

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

headed.

Drinking alcohol

Be careful drinking alcohol while you are taking Topreloc-xl.

If you drink alcohol, dizziness or light-headedness may be worse.

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

Topreloc-xl, like other beta-blocker medicines, tends 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.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Topreloc-xl. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too many Topreloc-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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel

well while you are taking Topreloc-xl.

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

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.

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

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

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

Tell your doctor or pharmacist if you have any of these mild side effects and they worry you.

Mild side effects

- 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

Tell your doctor or pharmacist immediately if you notice any of these serious side effects.

Serious side effects

- dizziness, light headedness or fainting especially on standing

up, which may be a sign of low blood pressure

- tingling or "pins and needles"
- coldness, burning, numbness or pain in the arms and/or legs
- 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
- problems with sexual function
- constant "flu-like" symptoms with tiredness or lack of energy
- unusual bleeding or bruising.

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

Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.

Very serious side effects

- shortness of breath, being less able to exercise
- swelling of the ankles, feet or legs
- chest tightness, wheezing, noisy breathing, difficulty 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.

These are very serious side effects. You may need urgent

medical attention or hospitalisation. These side effects are rare.

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.

You may not experience any of them.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

After using Topreloc-xl

Storage

Keep your Topreloc-xl tablets in the blister & bottle until it is time to take them.

If you take the tablets out of the box or blister pack they may not keep well.

Store below 25°C. Protect from moisture

24 months shelf life (for blister pack and HDPE bottle pack)

In-use shelf life (for HDPE bottle packs only) - 3 months at 25 °C from the date of opening.

Do not store Topreloc-xl or any other medicine in the bathroom or near a sink or stove. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep Topreloc-xl 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

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

Do not use this medicine after the expiry date.

Product description

This medicine is only available with a doctor's prescription

Topreloc-xl tablets are available in four different strengths:

- 23.75 mg
- 47.5 mg
- 95 mg
- 190 mg

What it looks like

- Topreloc-xl 23.75 mg tablets are white to off white, oval shape, biconvex film coated tablet with breakline on one side and debossed with 'A' and '3' on each side of breakline on other side.
- Topreloc-xl 47.5 mg tablets are white to off white, round shape, biconvex film coated tablet with breakline on one side and debossed with 'A50' on other side.
- Topreloc-xl 95 mg tablets are white to off white, round shape, biconvex film coated tablet with breakline on one side and debossed with 'A100' on other side.
- Topreloc-xl 190 mg tablets are white to offwhite, oval shape, biconvex film coated tablet with breakline on one side and debossed with 'A200' on other side.

Topreloc-xl available in a

23.75 mg:

- PVC/PVDC Blister Pack of 15's Tablets
- HDPE Bottle Pack of 15's, 30's, & 90's Tablets.

47.5 mg/95 mg/190 mg:

- PVC/PVDC Blister Pack of 15's & 30's Tablets
- HDPE Bottle Pack of 15's, 30's & 90's Tablets.

Ingredients

Active ingredient (main ingredient)

- Topreloc-xl 23.75 mg-23.75 mg metoprolol succinate per tablet
- Topreloc-xl 47.5 mg-47.5 mg metoprolol succinate per tablet
- Topreloc-xl 95 mg-95 mg metoprolol succinate per tablet
- Topreloc-xl 190 mg-190 mg metoprolol succinate per tablet

Other ingredients (inactive ingredients)

- Microcrystalline Cellulose
- Silicon dioxide
- Povidone
- Ethyl Cellulose
- Methacrylic Acid Copolymer
- Triethyl Citrate
- Talc
- Macrogol 6000
- Silicified Microcrystalline Cellulose
- Croscarmellose Sodium
- Sodium Stearyl Fumarate
- Opadry YS-1R-7006 Clear (ARTG # 13068)
- Opadry 02F280014 White (ARTG # 123088)

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

Who supplies this medicine

Sponsor

Topreloc-xl is supplied in Australia by:

Pharmacor Pty Ltd Chatswood NSW 2067 Australia

www.pharmacor.com.au

Telephone: 1300 138 805

Topreloc-xl is supplied in New Zealand by:

Pharmacor Limited c/- Wynn Williams Level 25, Vero Centre 28 Shortland Street Auckland Central AUCKLAND, 1010 New Zealand.

Ph: +64 800 172 553

or

0800 172 553

Date of Preparation

This leaflet was prepared in December 2025.

Australian Registration Number:

Topreloc-xl 23.75 mg:

Blister pack: 356239

Bottle pack: 356235

Topreloc-xl 47.5 mg:

Blister pack: 356233

Bottle pack: 356240

Topreloc-xl 95 mg:

Blister pack: 356243

Bottle pack: 356236

Topreloc-xl 190 mg:

Blister pack: 356232

Bottle pack: 356238