# TOPRELOC-XL

# metoprolol succinate

# **Consumer Medicine Information (CMI) summary**

The <u>full CMI</u> 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 TOPRELOC-XL?

TOPRELOC-XL contains the active ingredient metoprolol succinate. It belongs to a group of medicines called beta-blockers, which used to treat heart failure.

For more information, see Section 1. Why am I using TOPRELOC-XL? in the full CMI.

# 2. What should I know before I use TOPRELOC-XL?

Do not use if you have ever had an allergic reaction to TOPRELOC-XL 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 use TOPRELOC-XL? in the full CMI.

# 3. What if I am taking other medicines?

Some medicines may interfere with TOPRELOC-XL 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 TOPRELOC-XL?

**Take TOPRELOC-XL exactly as your doctor has prescribed.** Your doctor will tell you how much TOPRELOC-XL tablets to take each day.

More instructions can be found in Section 4. How do I use TOPRELOC-XL? in the full CMI.

# 5. What should I know while using TOPRELOC-XL?

Things you should do	<ul> <li>Remind any doctor, dentist or pharmacist you visit that you are using TOPRELOC-XL</li> <li>If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking TOPRELOC-XL</li> <li>Stop taking TOPRELOC-XL and contact your doctor immediately if you become pregnant while you are taking TOPRELOC-XL</li> </ul>
Things you should not do	<ul> <li>Do not give this medicine to anyone else, even if their condition seems similar to yours.</li> <li>Do not use it to treat any other complaints unless your doctor tells you to</li> </ul>
Driving or using machines	<ul> <li>Be careful before you drive or use any machines or tools until you know how TOPRELOC-XL affects you</li> <li>TOPRELOC-XL may affect your ability to drive a car or operate machinery</li> </ul>
Drinking alcohol	Tell your doctor if you drink alcohol.
Looking after your medicine	• Keep TOPRELOC-XL tablets in a cool dry place where the temperature stays below 25°C. It may be stored in a refrigerator but should not be frozen.

For more information, see Section 5. What should I know while using TOPRELOC-XL? in the full CMI.

# 6. Are there any side effects?

- 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.
- 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.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> effects? in the full CMI.

# **TOPRELOC-XL**

metoprolol succinate

### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using TOPRELOC-XL. 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 TOPRELOC-XL.

# Where to find information in this leaflet:

- 1. Why am I using TOPRELOC-XL?
- 2. What should I know before I use TOPRELOC-XL?
- 3. What if I am taking other medicines?
- 4. How do I use TOPRELOC-XL?
- 5. What should I know while using TOPRELOC-XL?
- 6. Are there any side effects?
- 7. Product details

# 1. Why am I using TOPRELOC-XL?

# 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 will have explained why you are being treated with TOPRELOC-XL and told you what dose to take.

Your doctor may have prescribed this medicine for another reason.

# 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.

# 2. What should I know before I use TOPRELOC-XL?

# Warnings:

#### Do not use TOPRELOC-XL if:

 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 low blood pressure
- you have a very slow heartbeat (less than 45-50 beats/minute)
- you have 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 these 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 betablocker medicines
- any other substances, such as 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

# 3. What if I am taking other medicines?

# Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get

# without a 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 betablocker 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.

#### 4. How do I use 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 / use

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

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

# If you take too much (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

# 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.

# 5. What should I know while using TOPRELOC-XL?

#### Things you should 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 should 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.

Looking after your medicine

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

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.

# 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?

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.

# Mild side effects

Mild side effects	What to do
<ul> <li>headache, tiredness, drowsiness, weakness, or lack of energy</li> <li>aches and pains, painful joints</li> <li>nausea (feeling sick), vomiting</li> <li>stomach upset, diarrhoea or constipation, weight gain</li> <li>dry mouth, changes in taste sensation</li> <li>difficulty sleeping, nightmares</li> <li>mood changes</li> <li>confusion, short-term memory loss, inability to concentrate</li> <li>increased sweating, runny or blocked nose</li> <li>hair loss</li> </ul>	Tell your doctor or pharmacist if you have any of the these mild side effects and they worry you.

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

#### Very serious side effects

Very serious side effects	What to do
<ul> <li>shortness of breath, being less able to exercise</li> <li>swelling of the ankles, feet or legs</li> <li>chest tightness, wheezing, noisy breathing, difficulty breathing</li> <li>chest pain, changes in heart rate or palpitations</li> <li>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</li> <li>yellowing of the skin or eyes (jaundice), generally feeling unwell.</li> <li>These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.</li> </ul>	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.

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.

#### 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 TOPRELOC-XL contains

I			
Active	TOPRELOC-XL 23.75 mg-		
ingredient	23.75 mg metoprolol succinate per		
	tablet		
(main			
ingredient)	TOPRELOC-XL 47.5 mg-		
	47.5 mg metoprolol succinate per		
	tablet		
	TOPRELOC-XL 95 mg-		
	95 mg metoprolol succinate per		
	tablet		
	TOPPEL OC MI 100		
	TOPRELOC-XL 190 mg-		
	190 mg metoprolol succinate per tablet		
Other			
	Microcrystalline Cellulose		
ingredients	Silicon dioxide		
(inactive	Povidone  File 1 G 11 1		
ingredients)	• Ethyl Cellulose		
	Methacrylic Acid Copolymer		
	Triethyl Citrate		
	• Talc		
	Macrogol 6000		
	• Silicified Microcrystalline		
	Cellulose		
	Croscarmellose Sodium		
	Sodium Stearyl Fumarate     No. 18, 700 (C)		
	• 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.

#### What TOPRELOC-XL 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 off white, 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.

#### Who distributes TOPRELOC-XL

Pharmacor Pty Ltd. Chatswood, NSW, 2067 Australia

# 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

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