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 TOPROL-XL?

TOPROL-XL contains the active ingredient metoprolol succinate. TOPROL-XL is used to treat heart failure. It is used in combination with other medicines to treat your condition.

For more information, see Section <u>1. Why am I using</u> <u>TOPROL-XL?</u> in the full CMI.

2. What should I know before I use TOPROL-XL?

Do not use TOPROL-XL if you have ever had an allergic reaction to TOPROL-XL or any of the ingredients listed at the end of the CMI, have or have had asthma, difficulty in breathing, wheezing, bronchitis or other lung problems in the past, have a history of allergic problems, including hayfever, have low blood pressure, have a very slow heartbeat, certain other heart conditions, have phaeochromocytoma which is not being treated already with other medicines, have a severe blood vessel disorder causing poor circulation in the arms and legs or you are receiving/having emergency treatment for shock or severely low blood pressure.

Talk to your doctor if you have any other medical conditions, take any other medicines including those not requiring prescription, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section <u>2. What should I know</u> before I use TOPROL-XL? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TOPROL-XL and affect how it works. A list of these medicines is in Section <u>3. What if I am taking other medicines?</u> in the full CMI.

4. How do I use TOPROL-XL?

- 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. More instructions can be found in Section <u>4. How do I use TOPROL-XL?</u> in the full CMI.

5. What should I know while using TOPROL-XL?

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Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using TOPROL-XL. Be sure to keep all of your doctor's
	all of your doctor's appointments so that your progress can be checked.
	 If you have to have any medical tests while you are taking TOPROL-XL, tell your doctor.
	 If you feel a worsening of your condition in the early stages of taking TOPROL-XL, tell your doctor immediately.
	 If you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor.
	 Tell your doctor immediately if you become pregnant while

	taking TOPROL-XL or develop any severe allergic reaction to foods, medicines or insect stings.
Things you should not do	 Do not stop using this medicine suddenly without checking with your doctor. Do not use TOPROL-XL to treat any other complaints unless your doctor tells you to.
Looking after your medicine	 Keep your tablets in the blister pack until it is time to take them. Keep the tablets in a cool dry place where the temperature stays below 30°C.

For more information, see Section <u>5. What should I know</u> while using TOPROL-XL? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience side effects, most of them are minor and temporary. However, some side effects may be serious and could require urgent medical attention or hospitalisation. For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

TOPROL-XL[™]

Active ingredient: metoprolol succinate

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using TOPROL-XL?

TOPROL-XL contains the active ingredient

metoprolol succinate. 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. It is used in combination with other medicines to treat your condition.

2. What should I know before I use TOPROL-XL?

Warnings

Do not use TOPROL-XL if:

 you are allergic to metoprolol succinate, or any of the ingredients listed at the end of this leaflet, or any other beta-blocker medicine or substances such as foods, preservatives or dyes.

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.

Always check the ingredients to make sure you can use this medicine.

- 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

Check with your doctor if you:

- are not sure whether any of the above apply to you
- have any other 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)

• 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 <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Children and adolescents

• Do not give TOPROL-XL to children.

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

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 and TOPROL-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 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.

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

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

4. How do I use TOPROL-XL?

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

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If you do not understand the instructions on the pack, ask your doctor or pharmacist.

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.

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

When to take TOPROL-XL

Take your medicine at about the same time each day, preferably together with the morning meal.

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

How long to take TOPROL-XL

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 TOPROL-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 use TOPROL-XL

TOPROL-XL should be used regularly at the same time each day. If you miss your dose at the usual time, **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 you missed.

 If you are not sure what to do or have trouble remembering when to take your medicine, ask your doctor or pharmacist.

If you use too much TOPROL-XL

If you think that you have used too much TOPROL-XL, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 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.

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.

5. What should I know while using TOPROL-XL?

Things you should do

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

Call your doctor straight away if you:

- become pregnant while taking TOPROL-XL.
- have a severe allergic reaction to foods, medicines or insect stings.

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, tell your doctor immediately.

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 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. 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, 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.

If you are about to be started on any new medicine, remind any doctor, dentist or pharmacist you visit that you are taking TOPROL-XL.

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

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.

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

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

Looking after your medicine

• 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place where the temperature stays below 30°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.

When to discard your medicine

Do not use TOPROL-XL if the expiry date (EXP) printed on the pack has passed or if the packaging is torn or shows signs of tampering.

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.

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

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

Less serious side effects

· · · · · · · · ·	beak to your doctor if bu have any of these
or lack of energy les	ss serious side effects ad they worry you.

Serious side effects

Serious side effects	What to do
 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 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. You may need urgent medical attention.

Serious side effects	What to do
 unusual bleeding or bruising. 	
Serious side effects are rare.	

Very serious side effects

Very serious side effects	What to do
 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. 	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. You may need urgent medical attention or hospitalisation.

Very serious side effects	What to do
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.

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 <u>www.tga.gov.au/reporting-problems</u>. 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 TOPROL-XL contains

Active ingredient

metoprolol succinate

(main ingredient)	
Other ingredients	 ethylcellulose phyprolose hypromellose microcrystalline
(inactive ingredients)	cellulose synthetic paraffin macrogol 6000 silicon dioxide sodium stearylfumarate titanium dioxide

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

What TOPROL-XL looks like

TOPROL-XL 23.75 mg tablets are white to off-white, oval, scored on both sides and marked A/Beta Symbol on one side. This tablet can be divided into equal doses. TOPROL-XL 23.75 mg comes in a blister pack of 15 tablets (AUST R 97785).

TOPROL-XL 47.5 mg tablets are white to off-white, round, scored on one side and marked A/mO on the other side. The score line is only there to help you break the tablet if you have difficulty swallowing it whole. TOPROL-XL 47.5 mg comes in a blister pack of 30 tablets (AUST R 97786). TOPROL-XL 95 mg tablets are white to off-white, round, scored on one side and marked A/mS on the other side. The score line is only there to help you break the tablet if you have difficulty swallowing it whole. TOPROL-XL 95 mg comes in a blister pack of 30 tablets (AUST R 97787).

TOPROL-XL 190 mg tablets are white to off-white, oval, scored on one side and marked A/mY on the same side. The score line is only there to help you break the tablet if you have difficulty swallowing it whole. TOPROL-XL 190 mg comes in a blister pack of 30 tablets (AUST R 97788).

Who distributes TOPROL-XL

AstraZeneca Pty Ltd ABN 54 009 682 311 66 Talavera Road MACQUARIE PARK NSW 2113

Telephone:- 1800 805 342

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