Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking MINAX?

MINAX contains the active ingredient metoprolol tartrate. MINAX tablets are used to lower high blood pressure (also called hypertension), prevent angina, treat or prevent heart attacks, or reduce your risk of heart complications following a heart attack or to prevent migraine headaches. For more information, see Section <u>1. Why am I taking MINAX?</u> in the full CMI.

2. What should I know before I take MINAX?

Do not use if you have ever had an allergic reaction to metoprolol tartrate or any of the ingredients listed at the end of the CMI. Do not use MINAX if you have asthma, or other lung problems, a history of allergies, low blood pressure, a very slow heartbeat or certain other heart conditions, phaeochromocytoma (a rare tumour of the adrenal gland) which is not being treated already with other medicines, a severe blood vessel disorder causing poor circulation in the arms and legs or if you are receiving emergency treatment for shock or severely low blood pressure.

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 <u>2. What should I know before I take MINAX?</u> in the full CMI.

3. What if I am taking other medicines?

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

4. How do I take MINAX?

- MINAX tablets are available as either 50 mg or 100 mg tablets. The dose of MINAX tablets depends on what condition you are being treated for. Your doctor will tell you what dose to take.
- Swallow the tablet with a glass of water.

More instructions can be found in Section <u>4. How do I take MINAX?</u> in the full CMI.

5. What should I know while taking MINAX?

Things you		
should do	• Be sure to keep all of your doctor's appointments so that your progress can be checked.	
	• If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.	
	• Make sure you drink enough water during exercise and hot weather when you are taking MINAX, especially if you sweat a lot.	
	• If you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor.	
Things you should not do	• Do not stop taking this medicine suddenly, or lower the dose, without checking with your doctor •	
Driving or using	• MINAX may cause dizziness, light-headedness, tiredness, or drowsiness in some people. Be careful	
machines	before you drive or use any machines or tools until you know how MINAX affects you.	
Drinking alcohol	• Combining MINAX and alcohol can make you more drowsy, dizzy or lightheaded.	
Looking after	• Keep your tablets in the original container until it is time to take them.	
your medicine	• Store in a cool dry place below 30°C away from moisture, heat or sunlight.	

For more information, see Section <u>5. What should I know while taking MINAX?</u> 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 effects?</u> in the full CMI.

Active ingredient: metoprolol tartrate

Consumer Medicine Information (CMI)

This leaflet provides important information about taking MINAX. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking MINAX.

Where to find information in this leaflet:

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

1. Why am I taking MINAX?

MINAX contains the active ingredient metoprolol

tartrate. MINAX belongs to a group of medicines called beta-blockers.

MINAX is used to:

- lower high blood pressure, also called hypertension
- prevent angina (chest pain)
- treat or prevent heart attacks, or reduce your risk of heart complications following a heart attack
- prevent migraine headaches

It works by changing 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 widens the blood vessels in the body, as well as helping the heart to beat more regularly.

Your doctor will have explained why you are being treated with MINAX and told you what dose to take. MINAX may be used either alone or in combination with other medicines to treat your condition.

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

Your doctor may have prescribed MINAX for another reason.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

2. What should I know before I take MINAX?

Warnings

Do not take MINAX if:

• you are allergic to metoprolol tartate, 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 asthma, wheezing, difficulty breathing or other lung problems, or have had them 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
- the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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

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

Check with your doctor if you:

- are not sure whether any of the above apply to you
- have any other medical conditions
- take any medicines for any other condition
- have any allergies to any other substances, such as foods, preservatives or dyes.

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, MINAX is not recommended for use during pregnancy.

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

The active ingredient in MINAX passes into breast milk, hence there is a possibility that the breastfed baby may be affected.

Children and adolescents

Do not give MINAX to children.

The safety and effectiveness of MINAX in children has not been established.

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

- asthma, wheezing, difficulty breathing or other lung problems
- diabetes
- an overactive thyroid gland
- liver problems
- kidney problems
- certain types of angina
- any other heart problems
- phaeochromocytoma, a rare tumour of the adrenal gland
- any blood vessel disorder causing poor circulation in the arms and legs.

If you have not told your doctor about any of the above, tell them before you start taking MINAX.

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 may interfere with MINAX and affect how it works. 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 or 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 indometacin and ibuprofen
- warfarin, a medicine used to prevent blood clots
- digoxin, a medicine used to treat heart failure
- medicines used to treat diabetes
- cimetidine, a medicine used to treat stomach ulcers
- medicines used to treat bacterial infections, for example rifampicin
- medicines used to treat depression
- monoamine-oxidase inhibitors (MAOIs).

These medicines may be affected by MINAX or may affect how well it works. You may need 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 MINAX.

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

4. How do I take MINAX?

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

They may differ from the information contained in this leaflet.

How much to take

For high blood pressure:

- The usual starting dose is one 50 mg or 100 mg tablet once a day for one week.
- The dose is then usually increased to 50 mg or 100 mg once or twice daily.
- Your doctor may tell you to take a different amount of MINAX.

Follow your doctor's instructions carefully.

If you are taking other prescription medicines which lower blood pressure, your doctor may need to change the dose of them to obtain the best results for you.

For angina pectoris:

• The usual dose is one 50 mg or 100 mg taken two or three times a day.

After myocardial infraction (heart attack):

• The usual dose is 100 mg taken twice a day, often starting with a lower dose for 2 days.

For migraine prevention:

• The usual dose is 50 mg to 75 mg taken twice a day (100 mg to 150 mg a day), taken in divided doses morning and evening.

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

They will tell you exactly how much to take.

How to take MINAX

Swallow the tablets with a glass of water.

MINAX tablets can be divided in half along the break-line, if your doctor has prescribed half a tablet.

When to take MINAX

Take your medicine at about the same time each day before or after food.

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 MINAX

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 MINAX 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 MINAX

If it is almost time for your next dose (within 6 hours), skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

If you take too much

If you think that you or anyone else has taken too much MINAX, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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. You may need urgent medical attention.

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

5. What should I know while taking MINAX?

Things you should do

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

Elderly patients especially need to be monitored to stop their blood pressure falling too far.

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 MINAX. 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.

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

If you do not drink enough water while taking MINAX, 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.

MINAX may affect how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar (also called hypoglycaemia) such as a fast heartbeat. MINAX 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 MINAX.

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

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

MINAX interacts with certain general anaesthetics and may cause a sudden drop in blood pressure.

If you have to have any medical tests while you are taking MINAX, tell your doctor. MINAX may affect the results of some tests.

Call your doctor straight away if you:

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

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

Things you should not do

• Do not stop taking MINAX suddenly, or lower the dose, without checking with your doctor.

Stopping MINAX suddenly may worsen your angina or cause other heart complications to occur. Your doctor may want you to gradually reduce the amount of MINAX you are taking before stopping completely.

- Do not give MINAX to anyone else, even if they have the same condition as you.
- Do not use MINAX 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 MINAX affects you.

As with other beta-blocker medicines, MINAX may cause dizziness, light-headedness, tiredness, or drowsiness in some people. Make sure you know how you react to MINAX 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.

Combining MINAX and alcohol can make you more drowsy, dizzy or lightheaded.

Things to be careful of

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

MINAX, like other beta-blocker medicines, may make you more sensitive to cold temperatures especially if you have circulation problems.

Looking after your medicine

• Keep your tablets in the original container until it is time to take them.

If you take MINAX out of the original container it will not keep well.

• Store below 30°C.

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

Store it in a cool dry place 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.

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.

When to discard your medicine

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

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take 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.

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

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

Less serious side effects

 headache, tiredness, drowsiness, weakness or lack of energy aches and pains, painful joints 	Speak to your doctor if you have any of these less serious side
 nausea (feeling sick), vomiting stomach upset, diarrhoea or constipation, weight gain dry mouth, changes in taste sensation difficulty sleeping, nightmares mood changes or depression confusion, short-term memory loss, inability to concentrate increased sweating, runny or blocked nose 	effects and they worry you.

hair loss

Serious side effects

Serious side effects	What to do
 dizziness, lightheadedness or fainting especially on standing up quickly, which may be due to low blood pressure tingling or "pins and needles" in the hands or feet coldness, burning, numbness or pain in the arms and/or legs skin rash or worsening of psoriasis symptoms of sunburn such as redness, itching and blistering, happening more quickly than usual abnormal thinking or hallucination buzzing or ringing in the ears, deafness dry or irritated eyes, blurred vision problems with sexual function constant "flu-like" symptoms with tiredness or lack of energy unusual bleeding or bruising 	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. 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 swallowing or breathing 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. 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.

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

Active ingredient	metoprolol tartrate 50 mg or
(main ingredient)	100 mg
Other ingredients (inactive ingredients)	 lactose monohydrate microcrystalline cellulose povidone colloidal anhydrous silica sodium starch glycollate magnesium stearate MINAX 100 mg also contains: purified talc carmellose sodium

Potential allergens	sugars as lactose and trace
	quantities of sulfites.

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

What MINAX looks like

MINAX 50 mg tablets are round, white, scored tablet marked ML/50 on one side and a Greek alpha symbol on the reverse. Each bottle contains 100 tablets. (AUST R 34408).

MINAX 100 mg tablets are round, white, scored tablet marked ML/100 on one side and Greek alpha symbol on the reverse. Each bottle contains 60 tablets. (AUST R 34410).

Who distributes MINAX

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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