MINAX® XL

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 XL?

MINAX XL contains the active ingredient metoprolol succinate. MINAX 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 taking</u> MINAX XL? in the full CMI.

2. What should I know before I take MINAX XL?

Do not take MINAX XL if you have ever had an allergic reaction to MINAX 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, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I take MINAX XL? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MINAX 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 take MINAX 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.
- MINAX XL tablets may be broken in half or swallowed whole with a glass of water as directed by your doctor.
 Do not chew or crush tablets. More instructions can be found in Section 4. How do I take MINAX XL? in the full CMI.

5. What should I know while taking MINAX XL?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using MINAX XL.
- Be sure to keep 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 MINAX XL, tell your doctor.
- If you feel a worsening of your condition in the early stages of taking MINAX 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 MINAX 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 MINAX 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 25°C.

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

MINAX® XL

Active ingredient(s): metoprolol succinate

Consumer Medicine Information (CMI)

This leaflet provides important information about taking MINAX 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 MINAX XL.

Where to find information in this leaflet:

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

1. Why am I taking MINAX XL?

MINAX XL contains the active ingredient metoprolol succinate. MINAX 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.

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

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

Your doctor may have prescribed MINAX XL for another reason.

2. What should I know before I take MINAX XL?

Warnings

Do not take MINAX XL if you:

- have an allergy to:
 - o any medicine containing metoprolol succinate
 - o any of the ingredients listed at the end of this leaflet
 - any other beta-blockers.
 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
 - o rash, itching or hives on the skin

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

- have or have had asthma (difficulty in breathing, wheezing and coughing), 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 (less than 45-50 beats/ minute)
- have certain other heart conditions
- have phaeochromocytoma (a rare tumour of the adrenal gland) which is not being treated already with other medicines
- low blood pressure (hypotension)you have a severe blood vessel disorder causing poor circulation in the arms and legs
- 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 allergies to any other medicines, foods, preservatives or dyes.
- have or have had any other medical conditions, especially the following:
 - asthma or other lung problems, even if you have had them in the past
 - o allergic problems, including hayfever

diabetes

- very slow heartbeat (less than 45-50 beats/minute)
- severe blood vessel disorder causing poor circulation in the arms and legs
- liver problems
- kidney problems
- o 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.

If you have not told your doctor about any of the above, tell him/ her before you start taking MINAX XL.

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</u>. Are there any side effects?

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant.

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

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

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

Children and adolescents

Do not give MINAX XL to children.

The safety and effectiveness of MINAX 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 MINAX 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 MINAX 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 MINAX 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 MINAX XL.

4. How do I take MINAX XL?

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

They may differ from the information contained in this leaflet.

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.

How to take it

- Halved tablet: Break the tablet into halves. Swallow a half tablet whole with a full glass of water.
- Whole tablet: swallow the tablets whole with a full glass of water.

Do not crush or chew the tablets.

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.

When to take MINAX 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 MINAX 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 MINAX 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 MINAX XL

If you forget to take a dose of MINAX XL, 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 for some hints.

If you take too much MINAX XL

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

You should immediately:

- phone the Poisons Information Centre (by calling 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.

If you take too many MINAX 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 taking MINAX XL?

Call your doctor straight away if you:

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

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

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.

You may feel light-headed or dizzy when you begin to take MINAX 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 MINAX XL, tell your doctor immediately.

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

If you do not drink enough water while taking MINAX 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.

MINAX XL may change how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar (hypoglycaemia). MINAX 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).
 - MINAX 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 MINAX XL.
- If you plan to have surgery (even at the dentist) that needs an anaesthetic, tell your doctor or dentist that you are taking MINAX XL.
- If you have to have any medical tests while you are taking MINAX XL, tell your doctor. MINAX XL may affect the results of some tests.
 - MINAX XL may affect the results of some tests.
- Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

Things you should not do

 Do not stop taking MINAX XL or change the dosage without checking with your doctor.

Your doctor may want you to gradually reduce the amount of MINAX 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 MINAX XL to anyone else even if they have the same condition as you.
- Do not use MINAX 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 MINAX XL affects you.

As with other beta-blocker medicines, MINAX XL may cause dizziness, light-headedness, tiredness, or drowsiness in some people. Make sure you know how you react to MINAX 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 MINAX 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 MINAX XL out of the blister pack it will not keep well.

Store it in a cool dry place where the temperature stays below 25°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.

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 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 the expiry date has passed take it to any pharmacy for safe disposal.

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 MINAX 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

Less serious side effects	What to do
 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 	Speak to your doctor if you have any of these less serious side effects and they worry you. These side effects are usually mild.

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" 	Tell your doctor as soon as possible if you notice any of these serious side effects. Serious side effects are rare.
 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 	

Serious side effects	What to do
 unusual bleeding or bruising. 	

Very serious side effects

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. These side effects are very 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 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 MINAX XL contains

Active ingredient (main ingredient)	Metoprolol succinate (23.75 mg, 47.5 mg, 95 mg, 190 mg per tablet)
Other ingredients (inactive ingredients)	microcrystalline celluloseethylcellulose

	 macrogol 400 hypromellose colloidal anhydrous silica macrogol 6000 sodium stearylfumarate OPADRY II complete film coating system 32K58900 WHITE
Potential allergens	Contains lactose

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

What MINAX XL looks like

MINAX XL modified release tablets are available in four (4) different product strengths:

 23.75 mg: White to off-white, round shaped, biconvex film coated tablets debossed with "M" on one side of break line on one side of the tablet and "MT1" on other side of the tablet (AUST R 205151).

Available in blister packs 15 tablets.

 47.5 mg: White to off-white, oval shaped, biconvex film coated tablet debossed with "M" on one side of break line on one side of the tablet and "MT2" on other side of the tablet (AUST R 205149).

Available in blister packs of 30 tablets.

 95 mg: White to off-white, oval shaped, biconvex film coated tablet debossed with "M" on one side of break line on one side of the tablet and "MT3" on other side of the tablet (AUST R 205148).

Available in blister packs 30 tablets.

 190 mg: White to off-white, oval shaped, biconvex film coated tablet debossed with "M" on one side of break line on one side of the tablet and "MT4" on other side of the tablet (AUST R 205150).

Available in blister packs 30 tablets.

Who distributes MINAX XL

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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