

MINAX[®] XL

metoprolol succinate modified release tablets

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about MINAX 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 benefits and risks. Your doctor has weighed the risks of you taking MINAX XL against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What MINAX XL is used for

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 this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before you take MINAX XL

When you must not take it

Do not take MINAX XL if you have an allergy to:

- any medicine containing metoprolol succinate
- 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
- rash, itching or hives on the skin

Do not take this medicine if you have or have had asthma (difficulty in breathing, wheezing and coughing), bronchitis or other lung problems in the past.

Do not take MINAX XL if you have the following conditions:

- a history of allergic problems, including hayfever
- a very slow heart beat (less than 45-50 beats/minute)
- a severe blood vessel disorder causing poor circulation in the arms and legs
- certain other heart conditions
- phaeochromocytoma (a rare tumour of the adrenal gland) which is not being treated with other medicines
- low blood pressure (hypotension)
- receiving/having emergency treatment for shock or severely low blood pressure.

Do not give this medicine to children.

Safety and effectiveness in children have not been established.

Do not take this medicine 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.

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 have allergies to any other medicines, foods, preservatives or dyes.

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

- 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 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 plan to breast-feed.

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

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from a 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
- anti-inflammatory drugs
- 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 different amounts of your medicines, 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 this medicine.

If you have not told your doctor about any of these things, tell them before you taken any MINAX XL.

How to take MINAX XL

Follow all directions given to you by your doctor and pharmacist 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

Halved tablet:

Break the tablet into half. Swallow halved 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.

DO NOT STOP TAKING MINAX XL TABLETS SUDDENLY.

The dose needs to be reduced slowly over at least 14 days to make sure your condition does not get worse. Your doctor will tell you how to reduce the dose.

When to take it

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 it

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

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 it

If you forgot 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 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.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) 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 MINAX XL. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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.

While you are taking MINAX XL

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking MINAX XL.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

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 become pregnant while taking this medicine, 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 MINAX 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 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 Dr 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.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take MINAX XL to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine 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.

Things to be careful of

Be careful driving or operating machinery 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.

Be careful when drinking alcohol while you are taking this medicine.

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).

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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MINAX XL.

If you get any side effects, do not stop taking MINAX 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 attention 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.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- 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.

The above side effects are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- 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.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Other side effects not listed here may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

You may not experience any of them. After taking MINAX XL

Storage

Keep your tablets in the pack until it is time to take them.

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

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store MINAX XL or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where 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 that is left over.

Product description

What it 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. 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. 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. 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. Available in blister packs 30 tablets.

Ingredients

MINAX XL contains 23.75 mg, 47.5 mg, 95 mg or 190 mg of metoprolol succinate as the active ingredient.

It also contains the following inactive ingredients:

- microcrystalline cellulose
- ethylcellulose
- macrogol 400
- hypromellose
- colloidal anhydrous silica
- macrogol 6000
- sodium stearyl fumarate

- . OPADRY II complete film coating system 32K58900
WHITE

MINAX XL contains lactose.

Supplier

MINAX XL is supplied in Australia by:

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

Australian registration numbers:

MINAX XL 23.75 mg:

AUST R 205151

MINAX XL 47.5 mg:

AUST R 205149

MINAX XL 95 mg:

AUST R 205148

MINAX XL 190 mg:

AUST R 205150

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