NEW ZEALAND CONSUMER MEDICINE INFORMATION

MYLOC CR

Metoprolol succinate controlled-release tablets 23.75 mg, 47.5 mg, 95 mg and 190 mg

What is in this leaflet

Please read this leaflet carefully before you start taking Myloc CR.

This leaflet answers some common questions about Myloc CR.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Myloc CR against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Myloc CR is used for

Myloc CR is used to treat:

- high blood pressure
- angina (a feeling of tightness, pressure or heaviness in the chest, usually bought on by stress or exercise)
- heart failure
- abnormal or irregular heart rate
- overactive thyroid gland.

Myloc CR is also used to help prevent migraines.

Myloc CR contains the active ingredient metoprolol succinate. It 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 widens the blood vessels in the body, causing blood pressure to fall, and 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 may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

Before you take Myloc CR

When you must not take it:

Do not take Myloc CR if you have an allergy to:

- any medicine containing metoprolol or to other betablockers
- any of the ingredients listed at the end of this leaflet.

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 give this medicine to a child under the age of 6 years.

Safety and effectiveness in children younger than 6 years have not been established.



Do not take Myloc CR if you have:

- asthma or other lung problems
- heart failure
- a very slow heart beat
- a severe blood vessel disorder causing poor circulation in the arms and legs
- low blood pressure
- certain other heart conditions.

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, including:

- phaeochromocytoma, a rare tumour of the adrenal gland
- diabetes.

Tell your doctor if you are pregnant or plan to become pregnant. Myloc CR is not usually recommended in pregnancy.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breastfeeding before you start taking Myloc CR.

Your doctor can discuss with you the risks and benefits involved.

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

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.

You should also tell any health professional who is prescribing a new medication for you that you are taking Myloc CR.

Some medicines and Myloc CR may interfere with each other. These include:

- other beta-blocker medicines, including beta-blocker eye drops
- other medicines used to treat high blood pressure, angina, an irregular heart beat or other heart conditions, including diltiazem, verapamil, hydralazine & nifedipine
- oral medications used to treat diabetes
- some antibiotics used to treat bacterial infections such as rifampacin
- medicines commonly used in emergency situations eg. adrenaline and certain anaesthetics
- some medicines used to treat depression such as monoamine oxidase inhibitors (MAOI) and selective serotonin reuptake inhibitors (SSRI).
- some antihistamines
- some anti-ulcer medication such as cimitedine
- medicines used to treat arthritis, pain or inflammation such as indometacin.

These medicines may be affected by Myloc CR 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 and pharmacist have more information on medicines to

be careful with or avoid while taking this medicine.

How to take Myloc CR

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 box, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you the dose of Myloc CR you need to take each day. This may depend on your age, the condition you are being treated for and whether or not you are taking other medicines.

Depending on your condition, your doctor may start your treatment with a low dose and slowly increase the dose.

The usual adult maintenance dose is between 47.5 mg and 190 mg, once daily. However this will vary depending on the condition being treated.

How to take it

Myloc CR tablets can be halved. The tablets and divided halves must be swallowed whole with a full glass of water. **Myloc CR tablets must not be chewed or crushed.**

Myloc CR can be taken with or without food.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it. In most conditions, Myloc CR should be taken in the morning.

How long to take it

Do not stop taking Myloc CR tablets suddenly. The dose needs to be reduced slowly over at least two weeks to make sure that your condition does not get worse.

If you forget to take it

If it is less than 12 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

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.

While you are using Myloc CR

Things you must do

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

If you become pregnant while taking this medicine, tell your doctor immediately.

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. Your blood pressure may drop suddenly if Myloc CR interacts with the anaesthetic.

If you are about to have any medical tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Tell your doctor as soon as possible if you notice your heart rate becomes very slow.

Your doctor may need to adjust your dose or you may need to stop Myloc CR completely.

If you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor.

Myloc CR may change how well your diabetes is controlled.

Things you must not do

Do not take Myloc CR 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 lower the dosage without checking with your doctor. If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. Your doctor may want you to gradually reduce the amount of Myloc CR you are taking before stopping completely. If possible this should be done over at least 2 weeks. Gradually reducing the dose may help reduce the possibility of your condition getting worse.

Things to be careful of

Be careful driving or operating machinery until you know how Myloc CR affects you.

This medicine may cause dizziness or fatigue in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

You may feel light-headed or dizzy when you begin to take Myloc CR.

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.

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

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

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) 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 Myloc CR. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too many Myloc CR tablets, your blood pressure may drop too low. You may faint, and your heart rate will also slow down or beat irregularly. You may also have nausea, vomiting, and convulsions. In extreme cases, serious heart and lung problems may occur. Occasionally generalised seizures may occur.

Side effects

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

This medicine helps most people, but it may have unwanted side effects in a few people. 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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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:

- cold hands and/or feet
- fatigue
- dizziness or light headed, especially when standing up
- headache
- nausea, vomiting, abdominal pain
- diarrhoea, constipation.

The above list includes the more common side effects of your medicine.

Other side effects can include:

- tingling or "pins and needles"
- muscle cramps
- dry mouth
- weight gain
- joint pain
- feelings of depression, nervousness, anxiety, confusion, memory loss
- sleeping disturbances or nightmares
- abnormal thinking or hallucinations
- sexual function problems
- slow or abnormal heartbeat
- breathlessness with exertion
- irritated eyes or blurred vision
- buzzing or ringing in the ears
- taste disturbances
- skin rash or worsening psoriasis
- hair loss
- increased sun sensitivity
- increased sweating
- aggravated diabetes mellitus.

The above list includes some 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:

- signs of allergy such as swelling of the face, lips or tongue which may cause problems with swallowing or breathing
- chest tightness, wheezing, shortness of breath, 'rattly breathing'
- fast, irregular heart beat, palpitations

- shortness of breath which may occur together with swelling of the feet or legs due to fluid build up
- coldness, burning, numbness or pain in the arms and/or legs
- unusual bleeding or bruising more easily than normal
- symptoms of hepatitis such as nausea, vomiting, fever, itching, yellowing of the skin and eyes, dark coloured urine.

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

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Myloc CR

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 Myloc CR 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-anda 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

Myloc CR tablets are available in four different strengths:

- 23.75 mg
- 47.5 mg
- 95 mg
- 190 mg

What it looks like

Myloc CR tablets are white to offwhite, oblong, film-coated tablets with break scores on both sides.

Ingredients

Myloc CR contains either 23.75 mg, 47.5 mg, 95 mg or 190 mg of metoprolol succinate as the active ingredient.

Myloc CR also contains:

- Macrogol
- Sugar spheres
- Polyacrylate dispersion 30%
- Talc
- Povidone
- Microcrystalline cellulose
- Magnesium stearate
- Silica colloidal anhydrous
 - Hypromellose
- Titanium dioxide.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Myloc CR is supplied in New Zealand by:

Viatris Ltd PO Box 11-183 Ellerslie AUCKLAND <u>www.viatris.co.nz</u> Telephone 0800 168 169

Date of Preparation

02 August 2024 (Based on datasheet dated 02 August 2024)