

DYNORMIN TABLET

Consumer Medication Information Leaflet (RiMUP)

Atenolol (50mg, 100mg)

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1. What Dynormin is used for

Dynormin contains the active ingredient atenolol. It belongs to a group of medicines called beta-blockers.

It is used to:

- control high blood pressure.
- relieve chest pain (angina pectoris).
- control irregular heart beat.
- protect the heart in the early treatment after a heart attack.

2. How Dynormin works

Dynormin works by slowing down the heart and reducing its workload.

3. Before you take Dynormin

When you must not use it

Do not take Dynormin Tablet and tell your doctor if you:

- are allergic (hypersensitive) to atenolol or any of the other ingredients in Dynormin Tablet – refer section 8.
- have second or third degree heart block.
- have shock caused by heart problems.
- have heart failure which is not under control.
- suffer with heart conduction or rhythm problems
- have a slow heart rate
- have low blood pressure.
- suffer from an increased acidity of the blood (metabolic acidosis)
- have or have had breathing problems such as asthma, difficulty breathing due to narrowing of the airways or reversible obstructive airways disease. Do not take this medicine if you have a history of wheezing or asthma. Consult your doctor or pharmacist first.

Before you start to use it

Take special care with Dynormin Tablet and tell your doctor if you:

- have a history of allergic reactions
- have heart problems such as heart failure, untreated congestive heart failure, ischaemic heart disease, poor heart function (poor cardiac reserve) or first degree heart block.
- suffer from blood circulation problems (which may cause your fingers and toes

to tingle or turn pale or blue) or cramping pain causing limping (intermittent claudication).

- suffer with diabetes mellitus (low blood sugar levels may be hidden by this medicine)
- have impaired liver or kidney function.
- are elderly.
- suffer from a tight, painful feeling in the chest in periods of rest (Prinzmetal's angina)
- have or have had psoriasis.
- suffer from treated pheochromocytoma (high blood pressure due to a tumour near the kidney).
- have high levels of thyroid hormone in the body (thyrotoxicosis).

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- clonidine (to treat high blood pressure)
- disopyramide, quinidine and amiodarone (to treat irregular heartbeat (arrhythmia))
- medicines to treat diabetes including insulin
- Non-Steroidal Anti-Inflammatory Drug (NSAIDs) e.g. indometacin
- digitalis glycosides such as digoxin (to treat heart conditions)
- nifedipine, diltiazem, verapamil, prazosin, alfuzosin and terazosin (to treat high blood pressure)
- sympathicomimetic agents (decongestant, asthma or heart medicine)
- isoprenaline or dobutamine (widens blood vessels)

Pregnancy and breast-feeding

If you are pregnant or planning to become pregnant, speak to your doctor before taking this medicine.

Breast-feeding is not recommended whilst taking Dynormin Tablet.

4. How to take Dynormin

How much to take

Doses:

Adults and children over 12 years

High blood pressure: 50-100mg a day as a single dose.

Angina: 100mg once a day or 50mg twice a day.

Irregular heart beat: initial treatment will usually be by injection, followed by a maintenance dose by mouth of 50-100mg a day as a single dose.

After a heart attack: initial treatment will usually be by injection, if no response followed by 50mg by mouth 15 minutes after the injection. A further 50mg 12 hours later.

Elderly

Your doctor may prescribe you a lower dose if you are elderly, especially if you have impaired kidney function.

Children under 12 years

Not recommended.

Patients with kidney failure

Your doctor may prescribe you a lower dose if you have kidney failure.

Mild to moderate kidney failure – 50mg a day.

Moderate to severe kidney failure – 50mg once every two days.

When to take it

Always take Dynormin Tablet exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist. Take the tablets with water

How long to take it

Continue taking Dynormin Tablet for as long as your doctor recommends.

Do not stop treatment early, especially if you have ischaemic heart disease. Talk to your doctor before you stop taking the tablets and follow their advice.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, unless it is nearly time for your next dose. Then go on as before. Never double up on the next dose to make up for the one missed.

If you take too much (overdose)

If you have accidentally taken more than the prescribed dose, contact your nearest casualty department or tell your doctor or pharmacist at once. Symptoms of an overdose include a slow or irregular heartbeat, low blood pressure, difficulty breathing due to fluid on the lungs, acute impaired heart function and shock, fainting.

5. While you are using Dynormin

Things you must do

Take your medicine exactly as your doctor has told you.

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

Tell your doctor immediately if you become pregnant while taking this medication.

Keep all appointments with your doctor. Your blood pressure should be checked regularly to determine your response to atenolol. Your doctor may ask you to check your pulse (heart rate). Ask your pharmacist or doctor to teach you how to take your pulse. If your pulse is faster or slower than it should be, call your doctor.

It is important for you to keep a written list of all of the prescription and non-prescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Dynormin to anyone else, even if they have the same symptoms or condition as you.

You are advised to avoid alcohol whilst taking this medicine.

Things to be careful of

Driving and using machines

Dynormin Tablet may cause dizziness or tiredness. Make sure you are not affected before driving or operating machinery.

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Anaesthetics and surgery

If you are going to have an operation or an anaesthetic, please tell your doctor or dentist that you are taking Dynormin Tablet as your heart beat might slow down too much and there may be an increased risk of developing low blood pressure.

6. Side effects

Like all medicines, Dynormin Tablet can cause side effects, although not everybody gets them.

Contact your doctor at once if you have the followings:

Skin rashes, dry eyes, coldness of the extremities, muscular fatigue and in isolated cases, bradycardia (abnormally slow heart rate). Sleep disturbances rarely occur. The incidence of side-effect is few and in most cases, the symptoms will disappear when treatment is ceased. Discontinue the drug if any side-effect is not explicable and consult the physician.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

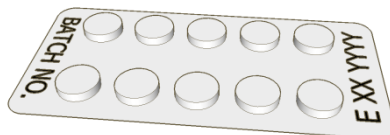
7. Storage and disposal of Dynormin

Storage

Keep out of the reach of children.

Do not store above 25°C. Keep the tablets in their original pack.

Do not use Dynormin Tablet after the expiry date which is printed on the edges of the blister strip. 'XX' represents the month when Dynormin Tablet can last be used, whereas 'YYYY' represents the year. The expiry date refers to the last day of that month.



Disposal

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. Product description

What it looks like

Dynormin Tablet 50mg - Round, biconvex and scored film-coated white tablets.

Dynormin Tablet 100mg - Round, biconvex and scored film-coated orange tablets.

Ingredients

Active ingredient

Dynormin Tablet 50mg & Dynormin Tablet 100mg - atenolol

Inactive ingredients

DYNORMIN TABLET 50mg - Sodium Starch Glycolate, Aerosil, Microcrystalline Cellulose, White Base, Coating Solution, Titanium Dioxide, Magnesium Stearate.
DYNORMIN TABLET 100mg - Sodium Starch Glycolate, White Base, Coating Solution, Titanium Dioxide, Magnesium Stearate, Aerosil, Microcrystalline Cellulose, Polyvinylpyrrolidone, Sunset Yellow.

MAL numbers

Dynormin Tablet 50mg - MAL19971838A
Dynormin Tablet 100mg - MAL19913259A

9. Manufacturer and product registration holder

DYNAPHARM (M) SDN BHD

2497, Mk. 1, Lorong Perusahaan Baru 5, Kawasan Perusahaan Perai 3, 13600 Perai, Pulau Pinang, MALAYSIA

10. Date of revision:

28 January 2014