

BETATAB 100MG TABLET

Metoprolol Tartrate 100mg

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What Betatab 100mg Tablet is used for

Betatab Tablet 100mg is used to treat:

- Hypertension: to reduce blood pressure and to reduce the risk of cardiovascular and coronary mortality (including sudden death), and morbidity.
- Angina pectoris (chest pain)
- Disturbances of cardiac rhythm including especially supraventricular tachycardia (irregular heartbeat or abnormal heart rhythm)
- Confirmed or suspected myocardial infarction (heart attack) - prevention of cardiac death and reinfarction.
- Functional heart disorders with palpitations (a fast-beating, fluttering or pounding heart).
- Migraine prophylaxis (treatment for migraine)
- Hyperthyroidism (overproduction of thyroid hormone by thyroid gland).

How Betatab 100mg Tablet works

Betatab 100mg Tablet slows the heartbeat, lessen the force with which the heart muscle contracts and reduce blood vessel contraction in the heart, brain, and throughout the body.

Before you use Betatab 100mg Tablet

-When you must not use it

Do not use Betatab 100mg Tablet and tell your doctor if you:

- allergic (hypersensitive) to metoprolol, other beta-blockers (drugs to treat high blood pressure and heart failure) or any of the other ingredients contained in Betatab Tablet 100mg.

- Have a heart block (the electrical signal that controls the heartbeat is partially or completely blocked)
- Have severe or uncontrolled heart failure
- Have a slow, regular heartbeat.
- Have a sick sinus syndrome (irregular heartbeat).
- Suffer from a tight, painful feeling in the chest in periods of rest (Prinz metal's angina).
- Have suffered a heart attack which has been complicated by a significantly slow heart rate.
- Suffer with blocked blood vessels, including blood circulation problems (which may cause your fingers and toes to tingle or turn pale or blue).
- Have an asthma and history of bronchospasm (difficulty in breathing).
- Suffer with untreated pheochromocytoma (high blood pressure due to a tumour near the kidney).
- Suffer from increased acidity of the blood (metabolic acidosis).
- Are given other medicines for blood pressure by injection especially verapamil, diltiazem or disopyramide.
- Have a low blood pressure.
- Suffer with diabetes associated with frequent episodes of low blood sugar (hypoglycaemia).
- Have or have had breathing difficulties or asthma including COPD (Chronic Obstructive Pulmonary disease-causing cough, wheezing or breathlessness, phlegm or increase in chest infections).

Pregnancy and Lactation

Betatab 100mg Tablet are not recommended during pregnancy or breastfeeding. Ask your doctor or pharmacist for advice before taking any medicine.

-Before you start use it

Before you use Betatab 100mg Tablet, your doctor needs to know if you have any of the following conditions. You may require a dose adjustment and your doctor would advise you accordingly after assessing your medical condition further.

- Congestive heart failure;
- Low blood pressure;
- Pheochromocytoma;

- Problems with circulation (such as Raynaud's syndrome);
- Asthma, bronchitis, emphysema;
- Diabetes;
- Depression;
- Liver or kidney disease;
- A thyroid disorder; or
- Severe allergies.

-Taking other medicines

Do not use Betatab 100mg Tablet if you are already taking:

- Monoamine Oxidase Inhibitors (MAOIs) for depression
- Other blood pressure lowering medicines such as verapamil, nifedipine and diltiazem
- Disopyramide or Quinidine (to treat irregular heartbeat (arrhythmia))

Before using Betatab 100mg Tablet, tell your doctor if you are already taking or have used recently any of the following medicines or are taking any non-prescribed medicines:

- Anaesthetic drugs (cyclopropane or trichlorethylene)
- Hypoglycaemic agent
- Calcium channel blockers drugs (verapamil or diltiazem or nifedipine)
- Sympathetic ganglion blocking agents
- Barbiturates drugs
- Phenothiazines
- Tricyclic antidepressants drugs
- Antihypertensive drugs
- Indomethacin or Celecoxib (Nonsteroidal Anti-Inflammatory Drugs [NSAIDs])
- Digitalis Glycosides and/or diuretics drugs
- Adrenaline (Epinephrine) or Noradrenaline (Norepinephrine), used in anaphylactic shock or other sympathomimetics.
- Enzyme inducing agents (Rifampicin)
- Enzyme inhibitors (Cimetidine, Hydralazine or Alcohol)
- Selective serotonin reuptake inhibitors (SSRIs) such as paroxetine, fluoxetine and sertraline, diphenhydramine, Hydroxychloroquine, Celecoxib or Terbinafine.
- Prazosin
- Class 1 antiarrhythmic drugs (disopyramide, quinidine, propafenone or amiodarone).
- Lidocaine (Metoprolol may impair the elimination of the drug).

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- Prostaglandin synthetase inhibiting drugs.
- Oestrogens such as a contraceptive pill or hormone replacement therapy.
- Xanthines such as Aminophylline or Theophylline.
- Aldesleukin.
- Alprostadil.
- Mefloquine drug
- Anxiolytics or hypnotics (Temazepam, Nitrazepam, Diazepam).
- Corticosteroids (e.g. Hydrocortisone, Prednisolone).

The list is not complete and there may be other drugs which interacts with metoprolol. Tell your doctor about all the medications you consume. This includes prescription drugs, over-the-counters, vitamins, and herbal products. Do not start a new medication without telling your doctor.

How to use Betatab 100mg Tablet

-How much to use

Always use Betatab 100mg Tablet exactly as advised by your doctor. If you are not sure, check with your doctor or pharmacist.

Swallow the tablet whole.

Usual doses:

- High blood pressure (Hypertension): Initially 1 tablet (100mg) daily. The dose may be increased to 2 tablets daily in single or divided doses.
- Angina Pectoris: 1 to 2 tablets (100-200mg) daily divided on 2 occasions.
- Irregular heartbeats (arrhythmia): 1 to 2 tablets (100-200mg) daily divided on 2 occasions.
- Hyperthyroidism: One and half tablet to 2 tablets (150-200mg) daily divided in 3 or 4 doses.
- Migraine Prophylaxis: 1 to 2 tablets (100-200mg) of Betatab 100mg Tablet daily divided on 2 occasions.
- Prophylactic Therapy After Myocardial Infarction: Maintenance Dosage:- 1 tablet (100mg) in the morning and evening.
- Functional Heart Disorders with Palpitations: 1 tablet (100mg) once daily in a single dose in the morning.
- Impaired Renal Function: The elimination rate is insignificantly affected by renal function, and dose adjustment is not needed in patients with impaired renal function.

- Impaired Hepatic Function: Betatab 100mg Tablet is given in the same dose to patients suffering from liver cirrhosis as to patients with normal liver function.

- Elderly: Dose adjustment is not needed.

- Children: Not recommended.

-When to use it

Use Betatab 100mg Tablet at the same time every day. The tablets should be taken on an empty stomach. The tablet can be divided in half if your doctor has advised you so. The half tablet should be swallowed whole, without chewing or crushing. Chewing or crushing the tablet could cause too much of the drug to be released at one time.

-How long to use it

The prescription is almost always lifelong. Your doctor would monitor your condition on regular basis and advice if a change is required. Do not stop taking Betatab 100mg Tablet without your doctor's advice. In some cases, you may need to stop taking it gradually.

-If you forget to use it

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

-If you use too much (overdose)

If you have accidentally used more than the prescribed dose, contact your nearest casualty department or tell your doctor or pharmacist at once. Symptoms of overdose are low blood pressure (fatigue and dizziness), slow and regular heartbeat (sinus bradycardia), heart conduction problems (heart block), heart failure, shock caused by heart problems, cardiac arrest, shortness of breath (bronchospasm), unconsciousness, coma, nausea, blue colouring of the skin (cyanosis), low blood sugar levels (hypoglycaemia) and high levels of potassium in the blood (hyperkalemia).

While you are using Betatab 100mg Tablet

-Things you must do

Use special care with Betatab 100mg Tablet and tell your doctor if you:

- Have a history of allergic reactions

- Have diabetes mellitus (low blood sugar levels may be hidden by this medicine)
- Suffer from treated pheochromocytoma (high blood pressure due to tumour near the kidney)
- Have an overactive thyroid (symptoms such as increased heart rate, sweating, tremor, anxiety, increased appetite or weight loss may be hidden by this medicine)
- Have or has suffered from psoriasis (severe skin rashes)
- Have a slow heart rate or blood vessel disorder
- Have controlled heart failure
- Have impaired liver or kidney function
- Have liver cirrhosis
- Are elderly.

-Things you must not do

Do not suddenly stop taking Betatab 100mg Tablet as this may cause worsening of heart failure and increase the risk of heart attack. Only change the dose or stop the treatment in consultation with your doctor.

-Things to be careful of

Glucose intolerance, total lactase deficiency or glucose-galactose malabsorption:

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains lactose.

Alcohol:

You are advised to avoid alcohol whilst taking this medicine. Alcohol may increase the blood pressure lowering effect of Betatab 100mg Tablet.

Driving and using machines:

Betatab 100mg Tablet may make you feel tired and dizzy. Make sure you are not affected before you drive or operate machinery, particularly after changing to another medicine or if used with alcohol.

Anaesthetics and surgery:

If you are going to have an operation or an anaesthetic, please tell your doctor or dentist that you are taking Betatab 100mg Tablet, as your heart beat might slow down too much.

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Side effects

Like all medicines, Betatab 100mg Tablet can cause side effects, although not everybody gets the effects. Stop treatment and contact a doctor at once if you have the following symptoms of an:

- Allergic reaction such as itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- General: Fatigue and dysgeusia (taste disturbances).
- Blood and lymphatic system: Thrombocytopenia (a low blood platelet which leads to poor blood clotting) and agranulocytosis (lowered white blood cell count).
- Psychiatric: Depression, nightmares, nervousness, anxiety, impotence, hallucinations, personality disorder, amnesia or memory impairment.
- Nervous system: Dizziness, headache, alertness decreased, somnolence or insomnia and paraesthesia (numbness, itching, and a feeling of pins and needles on skin).
- Eye: Visual disturbance (blurred vision, dry eyes and/or eye irritation).
- Ear: Tinnitus (ringing in the ears) and hearing disorders (hypacusis or deafness).
- Cardiac: Bradycardia (slow heart rate), heart failure, cardiac arrhythmias (Irregular heart rhythm), palpitation (fast heart beating), cardiac conduction disorders (heart block), precordial pain (chest pain) and increase in existing intermittent claudication (pain and cramping in the lower leg).
- Vascular: Orthostatic hypotension (fall in blood pressure when a person stands from a sitting position that leads to dizziness), oedema (swelling), Raynaud's phenomenon (causing pain, numbness, coldness and blueness of the fingers) and Gangrene in patients with pre-existing severe peripheral circulatory disorders.
- Respiratory: Exertional dyspnea (Shortness of breath during exercise), bronchospasm (difficulty in breathing) and rhinitis (stuffy nose, runny nose or sneezing).
- Gastrointestinal: Nausea, abdominal pain, diarrhoea or constipation and dry mouth.
- Hepatobiliary: Hepatitis (symptoms include fever, sickness and yellowing of the skin or whites of the eyes).

- Skin: Skin rash, photosensitivity (sun allergy), hyperhidrosis (abnormally excessive sweating), alopecia (baldness), worsening of psoriasis and occurrence of antinuclear antibodies (possibility to have autoimmune disorders).
- Musculoskeletal and connective tissue: Muscle cramps and arthritis (joint inflammation).
- Reproductive system and breast: Disturbances of libido (diminished or absent feelings of sexual interest).

If you notice any of these effects, and they get worse, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Betatab 100mg Tablet

-Storage

Keep all medicines out of the sight and reach of children. Do not use Betatab 100mg Tablet after its expiry date stamped on the pack.

Store below 30°C.

-Disposal

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

Product Description

-What it looks like

A white to off white, round, biconvex tablet with scoreline on one side.

-Ingredients

-Active ingredients

- Metoprolol Tartrate 100 mg

-Inactive ingredients

- Lactose Monohydrate
- Corn Starch
- Povidone K30
- Isopropyl Alcohol

- Talc
- Magnesium Stearate
- Croscarmellose Sodium
- Colloidal Silicon Dioxide

-MAL number:

MAL21056021AZ

Product Registration Holder and Manufacturer

Idaman Pharma Manufacturing Sdn. Bhd (661901-P)
Lot 24 & 25, Jalan Perusahaan Lapan, Bakar Arang Industrial Estate, 08000, Sungai Petani, Kedah Darul Aman, Malaysia.

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