METOHEXAL TABLET

Metoprolol Tartrate (50mg, 100mg)

What is in this leaflet

- 1. What Metohexal is used for
- 2. How Metohexal works
- 3. Before you use Metohexal
- 4. How to use Metohexal
- 5. While you are using it
- 6. Side effects
- 7. Storage and Disposal of Metohexal
- 8. Product Description
- 9. Manufacturer and Product Registration Holder
- 10. Date of revision

What Metohexal is used for

This medicine is used:

- To treat high blood pressure (hypertension)
- In management of heart attack (myocardial infarction)
- To treat irregular heart beat (arrhythmia)
- To treat coronary artery disease (narrowing of blood vessels)

How Metohexal works

Metohexal contains active ingredient, metoprolol that belongs to the 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.

Before you use Metohexal

- When you must not use it

Do not use Metohexal if you:

- With partial heat block
- Have severe heart failure
- With sinus bradycardia (sinus rhythm with a resting heart rate less than 45-50 beats/min
- With abnormal heart beat
- Have seriously poor blood circulation
- Are suffering from shock, due to your heart not pumping properly (cardiogenic shock)
- Have rare tumor in adrenal gland (phaeochromocytoma)
- Have very low blood pressure (hypotension)
- With obstructive airway disease or breathing difficulties of asthma
- Have heart attack with a very slow heart rate (less than 45 to 50 beats per minute)

- Before you start to use it

Tell your doctor if you:

- Have ever had reaction or been told that you are allergic to metaprolol tartrate or any other medicines in beta blocker group or any of the other Metohexal ingredients
- Have any breathing problems
- Have any heart problems
- Are a diabetic patient
- Going to have surgery
- Have excessive production of thyroid hormone
- Have any eye disorder
- Have any liver problems
- Are an elderly patient
- Have intolerant to galactose

- Taking other medicines

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription. You may need to use different amounts of these medicines, or you may need to take different medicines. Your doctor will advise you. In particular, tell your doctor if you take any of the following:

- Calcium channel blockers used to treat high blood pressure and angina e.g verapamil and diltiazem
- Other medicines used to treat high blood pressure including other beta blockers medicines
- Certain medicines used to treat abnormal or irregular heartbeat e.g procainamide and quinidine
- Nitroglycerin (to treat chest pain)
- General anesthetics
- Medicines for depression, e.g. fluvoxamine and fluoxetine
- Hydralazine, a medicine to treat high blood pressure
- Digitalis glycosides e.g. digoxin to treat heart failure
- Medicines for cardiac arrest and low blood pressure, e.g. adrenaline, noradrenaline
- Monoamine-oxidase inhibitors (MAOIs), used to treat depression
- Certain medicines used to relieve pain, swelling and other symptom of inflammation, including arthritis e.g. indomethacin
- Rifampicin, to treat bacterial infections
- Clonidine, medicines to treat high blood pressure
- Insulin and tablets to treat diabetes

- Lidocaine (local anesthetic)
- Prazosin (treat high blood pressure)
- Ergot alkaloid (treat migraine)
- Dipyridamole (prevent blood clots)

Avoid alcohol while on the Metohexal treatment.

Your doctor or pharmacist will have more information on the medicines you should avoid.

- Pregnancy and lactation

Please consult your doctor before start to use Metohexal if you are pregnant, plan to become pregnant, breast-feeding or intend to breast-feed. Your doctor will have weighed the risks of you taking Metohexal against the benefits they expect it will have for you.

How to use Metohexal

The information in this leaflet may not be the same as the instructions given to you by your doctor, as the treatment given is tailored according to your condition. Always take Metohexal exactly according to the instructions given to you by your doctor or pharmacist. Check with your doctor or pharmacist if you are not sure.

- How much to use

response.

<u>Hypertension (high blood pressure)</u>
The initial dose is 100 mg daily. Your doctor may increase the dose according to your

<u>Cardiac arrhythmias (irregular heart beat)</u> Metohexal is given as maintenance therapy with a dose of 50 mg to be taken three times daily.

Myocardial infarction (heart attack)

The initial dose is 50 mg to be taken every 6 hours for 2 consecutive days. The dose will be increased to 100 mg twice daily as maintenance dose.

- When to use it

Take Metohexal at the same time every day orally.

- How long to use it

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.

- If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally. If it is almost time for your next dose, 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 use too much (overdose)

If you or anyone else takes too many tablets, you should immediately go to your nearest hospital emergency department or tell your doctor. Do this even if there are no signs of discomfort or poisoning. Take the carton or any remaining tablets you have with you.

The main symptoms of over dosage are:

- Low blood pressure (dizziness, fainting, light-headedness)
- Heart insufficiency, heart failure
- Breathing difficulties
- Slow heart beat
- Nausea, vomiting
- Bluish discolouration of skin
- Irregular movement of the body
- Impaired consciousness or even coma
- Death may also be resulted

If you have any further questions on the use of this product, ask your doctor or pharmacist.

While you are using it

- Things you must do
- If you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor. Metohexal may change how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar (hypoglycaemia).
- Metohexal may increase the time your body takes to recover from low blood sugar. Your dose of diabetic medicine including insulin may need to change.
- Tell your doctor immediately if you develop a severe allergic reaction to any

food, medicine or insect sting while taking Metohexal.

- Make sure you drink enough water during exercise and hot weather when you are taking Metohexal, especially if you sweat a lot. If you do not drink enough water while taking Metohexal, you may feel faint or light-headed or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.
- You may feel light-headed or dizziness when changing position, especially during standing up or getting out of bed. This is because your blood pressure is falling 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.
- Elderly patients especially need to be monitored to stop their blood pressure falling too far.
- Things you must not do
- Do not stop taking your medicines without consulting your doctor. It is important to keep taking your medicine even if you feel well.
- Do not use Metohexal after the expiry date which is stated on the carton and blister.
- Do not give this medication to anyone else, even if they have the same condition as you.
- Things to be careful of
- This medicine may cause dizziness, headaches, and tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.
- If you drink alcohol, it may worsen the symptom of dizziness or light headedness.

Side effects

Like many medicines, Metohexal may cause side effects in some patients, particularly when you first taking them but not everyone will get it.

Please tell your doctor or pharmacist if you notice the following side effects that worry you:

- Common side effects:
- Nausea and vomiting
- Abdominal pain
- Fatigue

- Dizziness and headache
- Slow heart rate
- Low blood pressure when you stand up from sitting or lying down
- Breathing difficulties
- Rare side effects:
- Depression
- Nightmares
- Decreased level of consciousness
- Drowsiness and disturbances of sleep
- Paraesthesia (sensation of tingling, pricking or numbness)
- Heart failure
- Changes in heart rate or palpitations
- Fluid retention
- Raynaud's phenomenon (reduced blood flow in response to cold or stress)
- Bronchospasm (cough, wheezing and tightness in the chest)
- Diarrhea or constipation
- Skin rashes
- Muscle cramps
- Very rare side effects:
- Central nervous system effect (hallucinations)
- Low blood platelet count (bruising and slow blood clotting after injury)
- Blurred vision, dry eyes, eye irritation
- Ringing of the ears and transient loss of hearing
- Chest pain and heart block
- Death of the body tissue due to lack of blood supply
- Inflammation of the mucous membrane inside the nose
- Dry mouth
- Inflammation of liver
- Photosensitivity reaction and skin disease with red, itchy and scaly patches
- Excessive sweating
- Loss of hair
- Inflammation in the joint
- Impaired sexual function
- Weight gain
- Abnormal liver function test

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people. 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 <u>portal.bpfk.gov.my</u> (Consumers –> Reporting)

Storage and Disposal of Metohexal

- Storage

Keep your medicine in a cool dry place at temperature below 25° C.

Keep out of the reach and sight of children.

- <u>Disposal</u>

Do not use Metohexal after the expiry date which is stated on the carton and blister.

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

Product Description

- What it looks like

Metohexal 50 Tablet: White, round biconvex tablet with one-sided score notch.

Metohexal 100 Tablet: White, round, biconvex tablet with a score notch on one side.

Metohexal is available in packages of 20, 50 or 100 tablets.

- Ingredients

- Active ingredient

Metohexal 50 Tablet: 50 mg metoprolol tartrate

tartrate

Metohexal 100 Tablet: 100 mg metoprolol tartrate

- Inactive ingredients

Lactose monohydrate, maize starch, cellulose microcrystalline, magnesium stearate, colloidal silicon dioxide, hydroxypropylcellulose, calcium hydrogen phosphate, crospovidone

- <u>MAL number</u>

Metohexal 50 Tablet: MAL19950521AZ Metohexal 100 Tablet: MAL19950522AZ

Manufacturer

Salutas Pharma GmbH Otto-von-Guericke-Allee 1 D-39179 Barleben

For:

Hexal AG Industriestraβe 25 83607 Holzkirchen, Germany

Product Registration Holder

IMEKS Pharma Sdn. Bhd. No. 5 & 9, Jalan Udang Harimau 2, Medan Niaga Kepong, 51200 Kuala Lumpur, Malaysia.

Date of revision

30-July-2015

Serial Number

BPFK(R4/2)280715/00229