Package leaflet: Information for the user

Metoprolol Medical Valley 25 mg prolonged-release tablets
Metoprolol Medical Valley 50 mg prolonged-release tablets
Metoprolol Medical Valley 100 mg prolonged-release tablets
Metoprolol Medical Valley 200 mg prolonged-release tablets

metoprolol succinate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.>
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <Invented name> is and what it is used for

Metoprolol succinate belongs to a group of medicines called beta-blockers. Metoprolol reduces the effect of stress hormones on the heart during physical and mental effort. It leads to the heart to beat more slowly (heart rate decreases) in these situations.

<Invented name> is used to treat:
- high blood pressure (hypertension),
- a tight pain in the chest caused by insufficient oxygen to the heart (angina pectoris),
- irregular heart rhythm (arrhythmia),
- palpitations (feeling your heart beat) due to non-organic (functional) heart disorders,
- stable heart failure with symptoms (such as shortness of breath or swollen ankles), when taken together with other medicines for heart failure.

<Invented name> is used to prevent:
- further heart attacks or damage to the heart after a heart attack,
- migraine.

<Invented name> is used to treat high blood pressure in children and adolescents aged 6 - 18 years.

2. What you need to know before you take <Invented name>

Do not take <Invented name>
- if you are allergic to metoprolol succinate or any other beta-blocker or any of the other ingredients of this medicine (listed in section 6).

- if you have unstable heart failure, are receiving treatment to increase heart contractions
- if you have heart failure and your blood pressure keeps falling below 100 mmHg
- if you have a slow heart rate (less than 45 beats/min) or low blood pressure (hypotension)
- if you are in shock caused by heart problems
- if you have heart conduction problems (2nd or 3rd degree atrioventricular block) or heart rhythm problems (sick sinus syndrome)
- if you have severe blood circulation problems (severe peripheral arterial disease)

Warnings and precautions
Talk to your doctor or pharmacist before taking <Invented name>.
- if you recieve verapamil intravenously
- if you have blood circulation problems which may cause your fingers and toes to tingle or turn pale or blue
- if you have tight chest pain usually occurring during the night (Prinzmetal's angina)
- if you have asthma or other chronic obstructive lung diseases
- low blood sugar levels may be hidden by this medicine (diabetes mellitus)
- if you have a heart conduction disorder (heart block)
- if you are having treatment to reduce allergic reactions. <Invented name> may increase your hypersensitivity to the substances you are allergic to and increase the severity of allergic reactions
- if you have high blood pressure due to a rare tumour in one of your adrenal glands (phaeochromocytoma)
- if you have heart failure
- if you are going to have an anaesthetic, please tell your doctor or dentist that you are taking metoprolol tablets
- if you have increased acidity of the blood (metabolic acidosis),
- if you have severely impaired renal function
- if you are being treated with digitalis.

Children
This medicine is not recommended to be used by children under 6 years of age because it has not been studied in this age group.

Other medicines and <Invented name>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
- propafenone, amiodarone, quinidine, verapamil, diltiazem, clonidine, disopyramide and hydralazine, digitalis / digoxin (a medicine for cardiovascular disease)
- barbituric acid derivatives (antiepileptic drug),
- medicines for inflammation (e.g., indomethacin and celecoxib)
- adrenalin (drug in acute shock and severe allergic reaction)
- phenylpropanolamine (medicines to mucous membranes in the nose)
- diphenhydramine (medicines for allergic conditions)
- terbinafine (for fungal infection)
- rifampicin (an antibiotic)
- other beta-blockers (e.g. eye drops)
- MAO inhibitors (used to treat depression and Parkinson's disease)
- inhalation anesthetics (drugs for anesthesia)
- medicines used to treat diabetes, the symptoms of low blood sugar may be hidden. <Invented name> could increase the risk of severe hypoglycaemia when used with certain type of antidiabetic drugs called sulfonylureas (e.g. gliquidone, gliclazide, glibenclamide, glipizide, glimepiride or tolbutamide)
- cimetidine (a medicine for heartburn and acid regurgitation)
- paroxetine, fluoxetine, and sertraline (medicines for depression).

<Invented name> with food and drink
<Invented name> can be taken with or without food.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Do not take <Invented name> during pregnancy unless explicitly instructed by your doctor to do so. Beta-receptor blockers, including metoprolol succinate, can be harmful to the unborn child and result in premature labour. Metoprolol succinate may cause side effects such as slow heart rate in the newborn. Tell your doctor as soon as possible if you become pregnant whilst taking <Invented name>.

Metoprolol succinate passes into breast milk. Metoprolol succinate should not be taken during breast-feeding unless absolutely necessary. Although the amount of active substance ingested with milk probably poses no hazard to the child, your doctor should monitor the breast-fed infant's heart function.

Driving and using machines

<Invented name> 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 taken with alcohol.

<Invented name> contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take <Invented name>

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

<Invented name> prolonged-release tablet is a dosage form that provides a uniform effect through the day and should therefore be taken once daily with a glass of water preferably in the morning.
<Invented name> can be divided into equal doses.
<Invented name> tablets (or the divided halves) should not be chewed or crushed.
Your doctor will choose a suitable starting dose for your particular condition and monitor your progress. If necessary, this dose can be increased or reduced.

The recommended dose is:

Adults:

Therapeutic indication	**Total daily dose (to be taken once daily)**
High blood pressure (hypertension)	50-100 mg once daily.

Tight chest pain (angina pectoris)	100-200 mg once daily
Irregular heart beats (arrhythmia)	100-200 mg once daily
Preventive therapy following a heart attack	200 mg once daily.
Palpitations due to heart disease	100 mg once daily.
Prevention of migraine	100-200 mg once daily.
Patients with stable heart failure in combination with other medications	The starting dose is 12.5-25 mg once daily. The dose can be increased gradually as needed to a maximum 200 mg once daily.
Patients with impaired liver function	If you have severely impaired liver function your doctor may adjust the dose. Always follow your doctor's advice.

Use in children and adolescents
<u>High blood pressure</u>

The dose of <Invented name> for the treatment of high blood pressure in children from 6 years of age and adolescents depends on your child's or the adolescent's body weight. Your doctor will work out the correct dose.
The usual start dose is 0.5 mg/kg once a day. The dose will be adjusted to the nearest tablet strength. Your doctor may increase the dose to maximum 2.0 mg/kg once a day depending on blood pressure response. Doses above 200 mg once daily have not been studied in children and adolescents.

<Invented name> is not recommended in children under 6 years of age.

If you take more <Invented name> than you should
If you have taken more than the prescribed dose, contact your nearest casualty department or tell your doctor at once. You may, depending on the extent of overdose, experience more intense side effects and/or symptoms such as drop in blood pressure, slow regular or irregular pulse to the point of cardiac arrest, heart block, heart failure, bronchial spasm, shock, difficulty breathing, vomiting, impaired consciousness, seizures.

If you forget to take <Invented name>
If you forget to take a dose, take it as soon as you remember, then go on as before.
Do not take a double dose to make up for a forgotten tablet.

If you stop taking <Invented name>
Do not suddenly stop taking <Invented name> 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.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common (may affect more than 1 in 10 people)
- Tiredness

Common (may affect up to 1 in 10 people)
- dizziness, headache
- slow heartbeat, cold hands and feet and palpitations
- shortness of breath with strenuous physical activity,
- feeling sick, abdominal pain, vomiting, diarrhoea, constipation

Uncommon (may affect up to 1 in 100 people)
- depression, nigthmares, difficulty sleeping
- pins and needles,
- transient worsening of symptoms of heart failure,
- during a heart attack, blood pressure may be greatly reduced, cardiogenic shock in patients with acute myocardial infarction
- shortness of breath worsening of bronchial problems,
- hypersensitivity reactions of the skin,
- chest pain, fluid retention (swelling), weight gain.

Rare (may affect up to 1 in 1,000 people)
- a reduction in the number of platelets in the blood (thrombocytopenia),
- forgetfulness, confusion, hallucinations, nervousness, anxiety,
- taste changes,
- visual disturbances, dry or irritated eyes,

- heart conduction disturbances, heart rhythm disturbances,
- changes in liver function tests,
- worsening or new psoriasis (a type of skin disease), sensitivity to light, increased sweating, hair loss,
- impotence (inability to obtain an erection),
  ringing in the ears.

Not known (frequency cannot be estimated from the available data)
- impaired concentration,
- muscle cramps,
- eye inflammation,
- tissue death in patients with severe blood circulation problems,
- runny nose,
- dry mouth,
- inflammation of the liver (hepatitis),
- joint pain.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented name>

.Keep this medicine out of the sight and reach of children.
This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and/or bottle after 'EXP'. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What <Invented name> contains

The active substance is metoprolol succinate.
Each prolonged-release tablet contains 23.75 mg of metoprolol succinate corresponding to 25 mg metoprolol tartrate.
Each prolonged-release tablet contains 47.5 mg metoprolol succinate, corresponding to 50 mg metoprolol tartrate.
Each prolonged-release tablet contains 95 mg metoprolol succinate corresponding to 100 mg metoprolol tartrate.
Each prolonged-release tablet contains 190 mg metoprolol succinate corresponding to 200 mg metoprolol tartrate.

The other ingredients are:
Tablet core: Microcrystalline cellulose (E 460(i)), Ethylcellulose, Dibutyl Sebacate, Tributyl Acetylcitrate, Poly(vinyl acetate), Macrogol (E 1521), Povidone (E 1201), Silicified Microcrystalline Cellulose, Lactose Monohydrate, Colloidal Anhydrous Silica, Magnesium Stearate, Hypromellose, Talc (E 553b).
Tablet coating: Hypromellose, Titanium Dioxide (E 171), Macrogol (E 1521), Talc (E 553b).

What <Invented name> looks like and contents of the pack

What <Invented name> looks like

<Invented name> 25 mg prolonged-release tablets: White to off white, oval, approx 8.5 mm x 4.5 mm, biconvex prolonged-release tablets, debossed with C on one side and 69 on other side of break line and break line on other side.

<Invented name> 50 mg prolonged-release tablets: White to off white, oval, approx 12.0 mm x 6.0 mm, biconvex prolonged-release tablets, debossed with C on one side and 68 on other side of break line and break line on other side.

<Invented name> 100 mg prolonged-release tablets: White to off white, oval, approx 14.0 mm x 8.0 mm, biconvex prolonged-release tablets, debossed with C on one side and 67 on other side of break line and break line on other side.

<Invented name> 200 mg prolonged-release tablets: White to off white, oval, approx 18.5 mm x 9.5 mm, biconvex prolonged-release tablets, debossed with C on one side and 66 on other side of break line and break line on other side.

The tablets can be divided into equal doses.

Pack sizes

<Invented name> 25 mg prolonged-release tablets:
HDPE bottle with aluminium induction seal liner with child resistant cap containing viscose. Pack sizes: 30, 50, 100, 105, 112 prolonged-release tablets
HDPE bottle with aluminium induction seal liner with screw cap containing viscose. Pack sizes: 250 prolonged release tablets

<Invented name> 50 mg prolonged-release tablets:
HDPE bottle with with aluminium induction seal liner child resistant cap containing viscose. Pack sizes: 30, 32, 50, 100, 105, 112 prolonged-release tablets
HDPE bottle with aluminium induction seal liner with screw cap containing viscose. Pack sizes: 250 prolonged release tablets

<Invented name> 100 mg prolonged-release tablets:
HDPE bottle with aluminium induction seal liner with child resistant cap containing viscose. Pack sizes: 30, 50, 100, 105, 112 prolonged-release tablets
HDPE bottle with aluminium induction seal liner with screw cap containing viscose. Pack sizes: 250 prolonged release tablets

<Invented name> 200 mg prolonged-release tablets:
HDPE bottle with aluminium induction seal liner with child resistant cap containing viscose. Pack sizes: 30, 50, 100, 105 prolonged-release tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

LABORATORIOS LICONSA, S.A.
Avda. Miralcampo, Nº7, Pol. Ind. Miralcampo
19200 Azuqueca de Henares (Guadalajara)
Spain

This medicine is authorised in the Member States of the European Economic Area under the following names:

Denmark	Metoprolol Medical Valley
Germany	Metoaxiro 25 mg, 50 mg, 100 mg, 200 mg Retardtabletten
Norway	Metoprolol Medical Valley
Sweden	Metoprolol Medical Valley

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