

Package leaflet: information for the patient

Metoprolol succinate Sandoz® retard 25, tablets with controlled release 23.75 mg Metoprolol succinate Sandoz® retard 50, tablets with controlled release 47.5 mg Metoprolol succinate Sandoz® retard 100, tablets with controlled release 95 mg Metoprolol succinate Sandoz® retard 200, tablets with controlled release 190mg

metoprolol succinate

Read carefully the entire leaflet before you this medicine are going to use because there is important information in for you.

- Keep this leaflet. Maybe you need it later again necessary.
- Do you still questions? Then contact your doctor or pharmacist.
- Do not give this medicine to others , because it isonly for you to you prescribed. It can be harmful to others ,even if they have the same symptoms as you. Do
- you experience any side effects one of the side effects listed in section 4 are? Or do you experience a side effect that is not in this leaflet listed ? Then contactyour your doctor of pharmacist.

Contents of this leaflet:

1. What is Metoprolol succinate Sandoz retard and what for is this medicine used?
 2. When may you this medicine not use or must you extra careful with be?
 3. How do you use this medicine ?Possible
 4. side effects How
 5. How stores you this medicine?
 6. Contents of the package and other information
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1. What is Metoprolol succinate Sandoz retard and what is this medicine used for?

Metoprolol succinate Sandoz retard belongs to the group medicines that beta-blockers are called. They protect the heart against an excessive amount of activity.

Adults

For the treatment of a high blood pressure (hypertension), in a constricting painful sensation on the chest (angina pectoris) or arrhythmias, after a myocardial infarction to prevent a new myocardial infarction ,in case of an overactive thyroid (hyperthyroidism thyroid (hyperthyroidism) in for prevention of migraine attacks.

Children and adolescents aged 6-18 years:

For the treatment of a high blood pressure (hypertension).

2. When may you this medicine not use or must you be extra careful with be?

When may you this medicine not use?

- You are allergic to an of the substances in this medicine. These substances can you find in section 6 of this leaflet.

- You are hypersensitive to other antihypertensive medications of the same type as Metoprolol succinate Sandoz retard, namely the beta-blockers.
- You have disorders in the conduction of the heart (2nd- and 3rd-degree AV-block).
- You have acute heart failure or heart failure that is not under control, with fluid in the lungs (pulmonary edema) or a decreased blood pressure (hypotension).
- In a 'shock' caused by insufficient pumping function of the heart.
- You suffer from severe circulatory disorders.
- In a severely slowed heart rate (bradycardia).
- You are continuously or at intervals treated with certain medications that affect the pumping ability of the heart (namely beta-agonists).
- You have a certain disorder in the heart rhythm (Sick sinus syndrome) and you have not received a pacemaker.
- You have a heart attack (myocardial infarction) in combination with a slow heart rate, a low blood pressure or you are decompensated.
- You receive the medication verapamil by injection into a vein administered, because thereby the blood pressure can decrease, cardiac conduction disorders can occur and heart failure can develop.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before you use this medicine. Always inform the doctor(s) who treat you about which problems or diseases you still have under treatment. Metoprolol succinate Sandoz retard must with caution be administered.

Be extra careful with Metoprolol succinate Sandoz retard:

- if you want to stop. You cannot in fact not suddenly stop, because this chronic heart failure (reduced pumping ability of the heart) can worsen and the risk of a heart attack (myocardial infarction) and sudden death can increase. See for tapering advice the section 'If you stop using the use of this medicine';
- if you use other medications for support of the function of the heart. There can be a deterioration of the heart function occur;
- if you suffer from paroxysmal occurring shortness of breath due to spasm of the muscles and swelling of the mucous membrane of the airways often accompanied by coughing and the expectoration of mucus (asthma (bronchial)) and if you are treated with e.g. terbutaline. When the symptoms worsen. It may be necessary to adjust the dose;
- if you have diabetes (diabetes mellitus). Metoprolol can worsen the symptoms of a too low blood sugar level in your blood. The chance of this is however small;
- if your heart's insufficient pumping power has and you are not treated. In that case
- you may not use Metoprolol succinate Sandoz retard;
- if you suffer from an increasingly slowed heart rate (bradycardia). The dosage can be adjusted or gradually stopped; if you experience
- cold fingers and/or feet (also without use of medications, Raynaud's syndrome or intermittent claudication (intermittent claudication)). Metoprolol succinate Sandoz retard can worsen the symptoms. It is important that your doctor knows; if

- you need to be operated on . It is important that your important that your doctor know that you metoprolol use;
- if you simultaneously treated with digitalis (medicine that the pumping power of the heart enhances). It can necessary are the dosage to adjust or gradually to discontinue ;if
- you have severe impaired function of the liver have has. De dosage must if necessary be reduced;
- in a tumor of the adrenal medulla that may be associated with sudden severe increase in blood pressure, severe headache, sweating and accelerated heartbeat (pheochromocytoma).
- if you suffer from a severe hypersensitivity to certain certain substances. The shock (severe drop of the blood pressure, pallor, agitation, weak rapid pulse, clammy skin, reduced consciousness) due to a sudden strong vasodilation due to this (anaphylactic shock) can indeed be more serious ..

your doctor if one one of above-mentioned warnings for you applicable is, or that in the past has been.

There is no experience with the treatment of heart failure in patients:

- older than 80 years;
- with a restrictive and enlarged heart muscle;
- with a specific heart valve disorder;
- with a severely reduced liver- and kidney function;
- who less than 3 months ago a heart attack have had;
- with a congenital heart defect.

Do you still other medications?

Do you besides Metoprolol succinate Sandoz retard still other medications, inform you that short ago done or are you this perhaps soon do? Tell that that your doctor or pharmacist. This applies also for medications that you without prescription can obtain.

Use a medication card. You record on it which medications you use and in which dosage.

Let also others know which medications you use!

Metoprolol succinate Sandoz retard can the effect of some medications influence and vice versa.

This applies e.g. to:

- calcium antagonists, such as verapamil and diltiazem. These medications can namely the contraction of the heart (contractility of the heart) and the conduction of the heart (AV- conduction) negatively affect (see also the section 'When are you this medicine not use');
- rifampicin, a medicine against certain infections, because it reduces the amount metoprolol in the blood lowers;
- medicines against allergy (antihistamines), because they increase the amount of metoprolol in the blood increase;
- medications against (severe) depression (depression) of medicines against severe mental illness (antipsychotics), because they increase the amount metoprolol in the blood increase;

- certain group pain-relieving medicines with also a anti-inflammatory and antipyretic effect (COX-2 inhibitors), because they increase the amount metoprolol in the blood increase;
- ganglion blockers (medications for neurological disorders), MAO-inhibitors (medications against depression) and other beta-blockers (also in eye drops), because extra monitoring necessary is;
- clonidine, because it in combination with a beta-blocker the symptoms of high blood pressure in increased degree can cause to return;
- medications against cardiac arrhythmias (anti-arrhythmics), such as amiodarone and quinidine. These medications can the conduction time of the heart (AV-conduction) prolong and have a negative influence on the contractile force of the heart;
- anesthetics (see also the section 'When should you be extra careful with this this medicine?');
- indomethacin (certain analgesic medicine with also a anti-inflammatory and antipyretic effect), because it the blood pressure-lowering effect of metoprolol can reduce;
- insulin and oral medications against diabetes, because the blood sugar-lowering effect of these medications by beta-blockers can be strengthened. In that case will the dosage of these medications need to be adjusted;
- lidocaine, a medicine for arrhythmias, because metoprolol the excretion of lidocaine from the body can reduce;
- digitalis, a medicine that the pumping power of the heart increases, because simultaneous use with this medicine a slowed heart rate can cause;

What should you watch out for with alcohol?

Alcohol increases the amount metoprolol in your blood.

Pregnancy, breastfeeding and fertility

Are you pregnant, do you think you are pregnant to be, do you want to pregnant become or gives you breastfeeding? Then contact your doctor or pharmacist before you use this medicine.

Pregnancy:

Your doctor can Metoprolol succinate Sandoz retard prescribe during the pregnancy if the benefits of the use for you outweigh against the risks for the unborn child. If you Metoprolol succinate Sandoz retard have used until the delivery will your newborn child possibly the first two days after n/a the birth extra be checked.

Breastfeeding:

Metoprolol succinate Sandoz retard should not be used during the period that breastfeeding is given, unless the use necessary is considered . Metoprololis excreted via the breast milk . Atnormal dosages is the amount of metoprolol in the breast milk breast milk small. If your doctor prescribes you Metoprolol succinate Sandoz retard prescribes, then will your child be extra be monitored.

Fertility:

Data on fertility indicate not on particulars.

Driving ability and the use of machines

As far as known there are no adverse effects on the driving ability and the ability to operate machines to operate. In the event of occurrence of side effects such as fatigue or dizziness you should however take into account that this the reaction time adversely can affect.

Metoprolol succinate Sandoz retard contains glucose, sucrose and lactose

If your doctor has told you that you certain sugars not tolerate, contact your doctor before you take this medicine.

3. How do you use this medicine

? this medicine always exactly as your doctor or pharmacist you that has told. Are you unsure about the correct use ? Then contact your doctor or doctor or pharmacist.

The recommended dosage is:

Increased blood pressure (hypertension):

Initial dosage: once daily 1 tablet Metoprolol succinate Sandoz retard 50. Possibly to increase to 100-200 mg once daily.

When you suffer from a reduced function of the liver, may the doctor decide the dosage to reduce (for example up to 1 tablet Metoprolol succinate Sandoz retard 25).

Constricting painful sensation on the chest (angina pectoris):

100-200 mg once daily. Maximum 2 tablets Metoprolol succinate Sandoz retard 200 per day.

Arrhythmias:

100-200 mg once daily. If necessary can the doctor decide this dosage to increase.

Too rapid action of the thyroid gland (hyperthyroidism):

100-200 mg once daily. If necessary can the doctor decide this dosage to increase.

To prevent of migraine attacks:

100-200 mg once daily.

Heart attack:

After you first have started with regular metoprolol tablets, the maintenance dosage: once daily 1 tablet Metoprolol succinate Sandoz retard 200.

If you notice that Metoprolol succinate Sandoz retard too strong or just too weak works, consult then your doctor or pharmacist.

The tablets with controlled release must not be crushed or chewed, but should be taken whole or half tablets with water be taken.

Use in children and adolescents:

High blood pressure: In children aged 6 years and older the dosage depending on the body weight. Your doctor calculates the correct dose for your child.

The usual starting dose is 0.5 mg per kilogram body weight once daily, but may not higher be than 50 mg. There is chosen for the available tablet strength that is closest to the calculated dose is. Your doctor can the dose increase to 2.0 mg per kilogram body weight, depending on the effect on the blood pressure. Doses above 200 mg once daily are not studied in children and adolescents.

Use of Metoprolol succinate Sandoz retard is not recommended in children younger than 6 years.

Duration of the treatment

Metoprolol succinate Sandoz retard will usually long-term used be.

Have you too much of this medicine used?

When you too many of Metoprolol succinate Sandoz retard has used, then immediately contact your doctor or pharmacist. Symptoms may include: severely lowered blood pressure (hypotension), slowed heart rate (bradycardia), disorder in the conduction of the heart (AV-block), heart failure (insufficient pumping power of the heart) (decompensation cordis), shock caused by insufficient pumping function of the heart, cardiac arrest, shortness of breath due to spasm of the muscles of the airways (bronchospasm), consciousness disorders (or even coma), nausea, vomiting and blue discoloration of the lips, tongue, skin and mucous membranes due to a deficiency of oxygen in the blood (cyanosis).

Simultaneous use of alcohol, medications in high blood pressure, quinidine (medication for palpitations) or barbiturates (certain medications for epilepsy) worsens the symptoms.

Did you forget this medicine in to take?

Do not double dose to a missed dose in to catch up. If you missed taking a dose in to take, you can do this still do, unless it almost time is for your next dose. Follow in that case the normal dosing schedule.

If you stop using this medicine The treatment

with Metoprolol succinate Sandoz retard should generally not be suddenly discontinued , because sudden become discontinued, because this chronic heart failure (reduced pumping ability of the heart) can worsen and the risk of a heart attack (myocardial infarction) and sudden death can increase. The doctor will as a rule the dose gradually reduce over a period of at least 2 weeks.

Do you still other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine can also this medicine side effects have. Not everyone experiences with it to deal.

The following side effects are very common, common, sometimes, rarely or very rarely reported:

Very often (occur in more than 1 in 10 users)Nervous system
Nervous system: fatigue.

Often (occur in less than 1 in 10 users)Heart:

slowed heart rate (bradycardia),palpitations Blood vessels

:: due to through for example quickly standing up from a sitting or lying position sometimes accompanied by dizziness dizziness orthostatic hypotension),cold hands hands en feet, palpitations (palpitations)

Nervous system: dizziness, headache Respiratory system: shortness of breath on exertion

Gastrointestinal tract: nausea, abdominal pain, diarrhea, constipation

Sometimes (occur in less than 1 in 100 users)Heart:

worsening of symptoms of heart failure (insufficient pumping power of the heart), certain disorder in the conduction of the heart, leading to arrhythmias (heart block), fluid retention (edema), pain in the heart region; a 'shock' caused by insufficient pumping function of the heart (cardiogenic shock) in patients with sudden heart attack (acute myocardial infarction)

Nervous system: perceiving of tingling, itching or pins and needles without any cause for it (paresthesiaparesthesiaMuscles

:: muscle cramps Gastrointestinal tract: vomiting General: weight gain

Psychiatric: (severe) depression (depression), reduced alertness, drowsiness or insomnia, nightmares

Respiratory system: Shortness of breath due to spasm of the muscles of the airways

(bronchospasm), also in patients who do not have obstructions have of the airways Skin:

transient skin rash, increase in sweat production

Rare (occur in less than 1 in 1,000 users) Heart:conduction disorders conduction disorders, disorders in the heart rhythm (arrhythmias) Gastrointestinal tract: dry mouth

Liver: liver function disorders Psyche: nervousness, anxiety

Genital organs: impotence, decreased desire for sex

Nose: inflammation of the nasal mucosa characterized by a blocked nose, sneezing and discharge (rhinitis)

Eyes: disorders in vision ,, dry and/or irritated eyes, inflammation of the conjunctiva (conjunctivitis)

Skin: hair loss

Very rarely (occur in less than 1 in 10,000 less than 1 in 10,000 users)

Skin: necrosis of tissue in patients with severe circulatory disorders, photosensitivity to light, exacerbation of recurrent skin condition accompanied ongoing with scaly, dry skin rash (psoriasis)

Gastrointestinal tract: taste disorders

Blood: blood disorder (deficiency of platelets) accompanied ongoing with blue spots and bleeding tendency (thrombocytopenia)

Liver: liver inflammation (hepatitis) accompanied ongoing with jaundice (yellow discoloration of the skin or eyes)

Joints: joint pain (arthralgia)

Psyche: memory loss, confusion, perceptions of things that do not are (hallucinations), alienation from oneself or from one's own feeling (depersonalization)

Ears: tinnitus (tinnitus) Genital organs: impotence

The reporting of side effects

Do you experience side effects, please contact your doctor or pharmacist. This applies also to side effects that are not in this leaflet listed. You can side effects also report via the Dutch Side Effects Centre Lareb. Website: www.lareb.nl. By reporting side effects, you help us to gain more information to get about the safety of this medicine.

Never reduce the dosage or treatment temporarily) interrupt interrupt See See 'If you stop taking this medicine'. How do you store

5. this medicine? Store below 25°C

Keep out of sight and

Outside the vision and keep of children out.

After opening the bottle the tablets are still 6 months shelf-stable.

Do not use this medicine more after the expiry date. You find it on the packaging after "EXP". There is a month and a year. The last day of the month is the expiry date.

Do not flush medications down the sink or the toilet and do not throw them away in the trash. Ask your pharmacist what to do with medications you should do not use anymore. If you medications in the correct way dispose they are in a correct way destroyed and do not enter the environment end up.

6. Contents of the packaging and other information Which substances are in this medicine?
 - The active ingredient in this medicine is metoprolol succinate.
Metoprolol succinate Sandoz retard 25: a tablet contains 23.75 mg metoprolol succinate, equivalent with 25 mg metoprolol tartrate.
Metoprolol succinate Sandoz retard 50: a tablet contains 47.5 mg metoprolol succinate, equivalent to 50 mg metoprolol tartrate.
Metoprolol succinate Sandoz retard 100: a tablet contains 95 mg metoprolol succinate, equivalent with 100 mg metoprolol tartrate.
Metoprolol succinate Sandoz retard 200: one tablet contains 190 mg metoprolol succinate, equivalent with 200 mg metoprolol tartrate.
 - The other substances in this medicine are sucrose, corn starch, glucose (liquid), polyacrylate, talc (E553B), magnesium stearate (E470b), microcrystalline cellulose (E460), crospovidone, colloidal silicon dioxide (E551), lactose, hypromellose (E464), titanium dioxide (E171) and macrogol 4000.
 - Metoprolol succinate Sandoz retard 100 contains also yellow iron oxide (E172).

What does Metoprolol succinate Sandoz retard look like and how much is in a package?

Metoprolol succinate Sandoz retard 25, 50 and 200:

white, oblong tablet with score line on both sides. The tablet with score line can in two equal doses be divided.

Metoprolol succinate Sandoz retard 100:

light yellow, oblong tablet with score line on both sides.

The tablet with score line can in two equal doses be divided.

The tablets are packaged in polypropylene/aluminum or PVC-aclar/aluminum blister packaging in a cardboard box or in HDPE bottles.

Metoprolol succinate Sandoz retard 25, 50, 100 and 200: 10, 20, 28, 30, 50, 50x1 and 90 tablets with controlled release in blister packs and 30, 100, 250 and 500 tablets with controlled release in bottles.

Not all mentioned pack sizes are on the market available.

Holder of the authorization for marketing trade bring and manufacturer Marketing Authorization Holder:

Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Netherlands

Manufacturers:

Salutas Pharma GmbH

Otto-von-Guericke Allee 1

39179 Barleben Germany

Sandoz B.V.

Hospitaaldreef 29

1315 RC Almere

Netherlands

Lek Pharmaceuticals d.d.

Verovškova 57,

1526 Ljubljana

Slovenia

Lek Pharmaceuticals d.d. Trimlini 2D

9220 Lendava

Slovenia

This medicine is registered under number number:

RVG 32376: Metoprolol succinate Sandoz retard 25, tablets with controlled release 23.75 mg

RVG 32377: Metoprolol succinate Sandoz retard 50, tablets with controlled release 47.5 mg is

RVG 32378: Metoprolol succinate Sandoz retard 100, tablets with regulated release 95 mg is

RVG 32380: Metoprolol succinate Sandoz retard 200, tablets with regulated release 190 mg

This leaflet is last approved in January 2025 January 2025