

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

# Lopresor® Divitabs 200 mg

## Slow-release film-coated tablets

**The active ingredient:**

Each tablet contains: Metoprolol tartrate 200 mg

**Inactive ingredients:** See section 6 "Further information".

**Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. Keep this leaflet. You may need to read it again. This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

**1. WHAT IS THE MEDICINE INTENDED FOR?**

The medicine is intended for the treatment of hypertension, angina pectoris and irregular heart rate, for the prevention of migraine and for the prevention of recurrent myocardial infarction.

Lopresor Divitabs dilates the blood vessels, thereby reducing the blood pressure.

**Therapeutic group:** Beta receptor blockers.

**2. BEFORE USING THE MEDICINE**
 **Do not use the medicine if:**

- you are sensitive (allergic) to metoprolol or to any of the additional ingredients contained in the medicine (see section 6 "Further information") or to any other medicine of the beta receptor blockers group.
- Some of the symptoms of an allergic reaction can include rash, itching or hives; swelling of the face, lips, tongue or other parts of the body; breathlessness, wheezing or breathing problems.
- you have one of the following medical conditions:
  - o asthma, wheezing, difficulty breathing or other severe lung problems, or if you had these problems in the past.
  - o very slow heart rate, lower than 45-50 beats per minute.
  - o low blood pressure.
  - o severe blood vessel disorder that causes poor circulation in the limbs (arms and legs).
  - o a rare tumor of the adrenal gland (pheochromocytoma) that is not being treated with other medicines.
  - o other certain heart problems.

If you are not sure whether any of the medical conditions listed above apply to you, check with your doctor.

**Special warnings regarding use of the medicine**

**Before starting to use Lopresor Divitabs, tell the doctor if you are allergic to:**

- other medicines, food, dyes or preservatives
- bee or wasp stings.

The doctor will want to know if you have a tendency to allergies. Beta receptor blockers can make an allergic reaction worse.

Tell the doctor if you have one of the following medical problems:

- o heart problems
- o high level of sugar in the blood (diabetes)
- o overactive thyroid gland

- o liver problems
- o certain types of angina, including Prinzmetal angina or Variant angina (chest pain when resting).
- o poor circulation in the limbs (e.g., very cold and pale palms of the hands or feet, or leg muscle pain when walking)
- o a tumor of the medulla of the adrenal glands (pheochromocytoma) - treatment will be necessary, in addition to Lopresor Divitabs
- o If you are undergoing surgery under anesthesia during treatment with Lopresor Divitabs
- o respiratory diseases such as asthma
- o a severe syndrome named oculomucocutaneous syndrome, whose signs include severe conjunctivitis, skin rash and ear infection

Tell the doctor if you notice or experience any of the following conditions during treatment with Lopresor Divitabs:

- spontaneous bleeding or bruising
- very slow or irregular heart beat
- yellow skin and eyes, nausea, loss of appetite and dark urine
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs
- hallucinations

**If you have one or more of the symptoms listed above, inform the doctor immediately.**

Your doctor may want to take special precautionary measures if you have any of the symptoms listed above.

**If you experience an allergic reaction to food, another medicine, or to an insect bite during treatment with Lopresor Divitabs, refer to the doctor immediately.** Lopresor Divitabs may make the allergic reaction worse or more difficult to treat.

**If you feel dizzy or faint when getting out of bed or standing up, do so slowly.**

You may feel dizzy at the beginning of treatment; this is caused by a sudden drop in blood pressure. If the problem does not pass on its own, consult the doctor.

To avoid symptoms of low blood pressure, here are some helpful hints for you:

- Stand up slowly to allow your body to get used to the change in position and blood pressure
- If you feel dizzy, sit or lie down until you feel better
- If you feel faint, breathe deeply and bend forward with your head between your knees
- Take extra care when exercising, driving or standing for long periods, especially in hot weather. Drink plenty of fluids, especially if you sweat a lot.

**If you are being treated for diabetes, be sure to check your sugar levels regularly and report any problem to your doctor.** Lopresor Divitabs may affect your diabetic control. Warning signs indicating low sugar levels, such as fast heart beat, may not occur and the duration of time with low blood sugar levels may be longer. The dosage of your diabetic medicines may have to be changed.

**If you are planning to undergo surgery and there will be a need for anesthesia, tell the doctor or dentist that you are taking Lopresor Divitabs.** This information will help the doctor to prevent undesirable side effects, such as a sudden drop in blood pressure.

**Be sure to wear warm clothing in cold weather, especially if you will be outdoors for a long time.** Like other beta blockers, Lopresor Divitabs may cause you to be hypersensitive to low temperatures, especially if you are suffering from circulation problems. The medicines in this group tend to decrease circulation to the skin, fingers and toes.

**Before starting to use new medicines, tell the doctor and pharmacist that you are taking Lopresor Divitabs. Tell any other doctor, dentist or pharmacist treating you that you are being treated with Lopresor Divitabs.**

**Children and adolescents:**

The medicine is not intended for children. There is not sufficient information about use of the medicine in children.

**Tests and follow-up:**

- if you suffer from heart problems, the doctor may perform a blood test and monitor your heart function.
- if you suffer from a high blood sugar level (diabetes), the doctor may check your blood sugar level regularly.
- if you suffer from hyperthyroidism, the doctor may check your thyroid and heart function regularly.
- if you are taking or have recently taken other medicines, the doctor may perform certain blood tests and monitor your heart function.

**Drug interactions:**

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** In particular, if you are taking:

- other beta blockers, including eye drops
- other medicines used to treat high blood pressure e.g., calcium channel blockers and clonidine
- antidepressants from the monoamine oxidase (MAO) inhibitor group
- other medicines used to treat irregular heart beat (arrhythmias)
- medicines used to treat diabetes
- indomethacin, a medicine used to relieve joint pain (arthritis) or inflammation
- cimetidine, a medicine for gastric ulcer
- local or general anesthetics used during surgery
- antidepressants (e.g., fluoxetine, paroxetine or bupropion)
- antipsychotic medicines (e.g., thioridazine)
- medicines to treat HIV/AIDS (e.g., ritonavir)
- medicines to treat allergy/hay fever (e.g., diphenhydramine)
- medicines to treat malaria (e.g., hydroxychloroquine or quinine)
- antifungals (e.g., terbinafine)
- ergot alkaloids - a group of medicines used to prevent and treat migraines
- dipyridamole - a medicine used to reduce the risk of blood clots
- other medicines that may cause a decrease in heart rate (e.g., fingolimod, a medicine used to treat multiple sclerosis)
- other medicines that may cause a decrease in blood pressure (e.g., aldesleukin, a medicine used to treat kidney cancer)

**You may need to change the dosages or the medicines or the medicines themselves.**

**Use of the medicine and food:**

You can take Lopresor Divitabs with or without food, according to the doctor's recommendation.

**Pregnancy, breastfeeding and fertility:**

**Tell the doctor if you are pregnant**

If you are pregnant or breastfeeding, consult the doctor or pharmacist before using the medicine. Lopresor Divitabs may affect your baby, especially if you take the medicine a few days before giving birth. The doctor will discuss with you the possible risks and benefits of taking Lopresor Divitabs during pregnancy.

**Tell the doctor if you are breastfeeding or are planning to breastfeed**

If you are breastfeeding, or planning to breastfeed, consult the doctor.

The active ingredient in Lopresor Divitabs passes into breast milk and there is a chance that your baby will be affected.

**Driving and using machines:**

Be careful driving, operating machinery or performing activities that require you to be alert while you are taking Lopresor Divitabs, until you know how it affects you. As with other

beta blockers, Lopresor Divitabs may cause dizziness, a mild headache or reduced alertness in some people. If you have any of these symptoms, do not drive or engage in any other activity that may be dangerous.

**3. HOW SHOULD YOU USE THE MEDICINE?**

Always use this preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation. The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally 100 to 200 mg per day. Depending on your response to the treatment, the doctor may suggest a higher or lower dosage. Take Lopresor Divitabs once a day, in the morning. If necessary, and according to the doctor's recommendation, take again in the evening.

**Do not exceed the recommended dose.**

**Instructions for use:**

Swallow the tablet without chewing, with a glass of water. Lopresor Divitabs can be taken with or without food. If needed, and according to the doctor's recommendation, the tablet can be halved along the score line. Then, swallow the half-tablet whole, without chewing, with a glass of water.

**Duration of treatment:**

**Continue taking the medicine for as long as the doctor instructs you to.**

Lopresor Divitabs helps you to control symptoms, but does not cure your ailment. The doctor will check your progress to confirm that the medicine is working and will decide how long the treatment will be. If you are uncertain, talk to the doctor.

**If you accidentally took a higher dosage:**

Symptoms of an overdose may include: feeling sick and vomiting, blue discoloration of the skin and nails, slow heart beat or an irregular heart beat; very low blood pressure; breathlessness; difficulty breathing when lying down; swelling of the feet; fainting; convulsions; nausea; vomiting; blue discoloration of the lips, tongue and skin; seizures; loss of consciousness; sudden and oppressive chest pain and death.

**If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you. You may require medical care.**

**If you forget to take the medicine**

If it is almost the time for the next dose (e.g., in approximately another 2-3 hours), skip the missed dose and take the next dose according to the regular dosing schedule.

Otherwise, take the dose as soon as you remember, and then continue taking the medicine according to the regular dosing schedule.

If you forgot to take the medicine at the designated time, do not take a double dose. This may increase the chance that you will experience undesirable side effects. Take the next dose at the regular time and consult the doctor.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the doctor.

**If you stop taking the medicine:**

The doctor may want to gradually reduce the dosage before stopping treatment.

This will help to reduce the chance of your condition worsening or of onset of undesirable heart problems.

**Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**

**If you have further questions regarding use of the medicine, consult the doctor or pharmacist.**

**4. SIDE EFFECTS**

**Tell the doctor or pharmacist as soon as possible if you do not feel well while using the medicine.**

As with any medicine, use of Lopresor Divitabs may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them. Patients over the age of 65 have an increased chance of experiencing side effects.

**Refer to a doctor or pharmacist if you have any question. Some side effects may be serious and you may require medical care:**

Immediately refer to a doctor or proceed to the closest hospital emergency room if you notice any of the following conditions:

- signs of allergy such as swelling of the face, lips or tongue, which may cause problems with swallowing and breathing
- chest tightness, wheezing, breathing difficulties
- shortness of breath, sometimes with tiredness, weakness or reduced ability to exercise
- swelling of the feet or legs due to fluid buildup
- cold sensation, burning, numbness or pain in arms and legs
- chest pain
- changes in heart rate (slow, fast, irregular)
- yellowing of the skin or eyes (jaundice), sometimes with pain in the abdomen
- symptoms accompanied by a constant sick feeling (chills, fever, sore throat, aching joints, swollen glands, tiredness or lack of energy)
- unusual bleeding or bruising
- skin reactions (rash, itching, worsening of psoriasis)
- symptoms of sunburn (redness, itching, swelling, blistering) that occur much faster than usual
- abnormal thinking or hallucinations (seeing or hearing things that are not there)
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs, signs of heart disorders
- numb or cold toes and fingers, possible signs of Raynaud's syndrome

The above mentioned side effects may be serious; you may need medical treatment.

**Additional side effects**

**Refer to the doctor if you experience one or more of the following side effects and they are bothersome for you:**

**Common side effects - effects that occur in 1-10 in 100 users:**

- dizziness
- light-headedness or fainting
- headache
- nausea or vomiting
- abdominal pain
- fatigue

**Rare side effects - effects that occur in 1-10 in 10,000 users:**

- muscle cramps
- nightmares
- depression or other mood changes
- diarrhea or constipation
- difficulty breathing with wheezing or coughing
- swelling
- palpitations
- decreased alertness, somnolence or insomnia (sleeping problems)
- numbness, tingling in the extremities, signs of paresthesia

**Very rare side effects - effects that occur in less than one in 10,000 users:**

- dry or irritated eyes, blurred vision
- buzzing or ringing in the ears
- difficulty hearing
- dry mouth
- increased sweating

- runny nose
- weight gain
- hair loss
- abnormal liver function test results
- gangrene in patients with pre-existing, severe peripheral circulatory disorders
- worsening of thickened patches of red/silver skin - signs of worsening of psoriasis
- joint pain and stiffness, signs of arthritis
- sexual function problems
- changes in ability to achieve or maintain an erection
- lower back pain, kidney disorder, increased blood pressure, blood clots - are possible signs of rapid proliferation of fibrous tissue in the part of the body (named retroperitoneum) that contains the kidneys, aorta, renal system and various other organs

**Side effects of unknown frequency:**

- confusion
- abnormal values of triglycerides in the blood
- abnormal values of cholesterol in the blood

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.**

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

**5. HOW SHOULD THE MEDICINE BE STORED?**

Avoid poisoning! This medicine, and any other medicine, must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Store below 30°C.

Do not store different medicines in the same package.

**6. FURTHER INFORMATION**

**In addition to the active ingredient, the medicine also contains:**

Magnesium stearate; silica, colloidal anhydrous; calcium hydrogen phosphate dihydrate; cellulose, microcrystalline; glyceryl palmitostearate; hypromellose; eudragit NE 30 D; iron oxide yellow, polysorbate 80; titanium dioxide; talc.

What the medicine looks like and the contents of the package:

A film-coated capsule-shaped, light yellow, convex tablet with a deep score line on both sides. CG/CG is printed on one side and CDC/CDC is printed on the other side. Each package has 14 tablets.

**Registration Holder and address:** Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

**Manufacturer and address:** Novartis Sağlık, Gıda ve Tarım Ürünleri, San.ve tic. A.Ş., Turkey, for Novartis Pharma AG, Switzerland.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health: 045 04 22324