

This medicine can be sold with a physician's prescription only.

## VASODIP® , Tablets

**Vasodip 10, Tablets**  
Lercanidipine hydrochloride 10 mg  
**Vasodip 20, Tablets**  
Lercanidipine hydrochloride 20 mg

Inactive ingredients are listed in section 6.

**Read this entire leaflet carefully before you start using this medicine.**

This leaflet contains concise information about the medicine. If you have any further questions, refer to your physician or pharmacist.

This medicine has been prescribed for you only. Do not pass it to others. It may harm them, even if you think that their medical condition is the same as yours.

This medicine is not intended for children under 18 years of age.

### 1. What is the medicine used for?

For the treatment of mild to moderate high blood pressure.

**Therapeutic group:** calcium channel blockers of the dihydropyridine derivative

### 2. Before using this medicine

**Do not use this medicine if:**

- You are pregnant or breastfeeding, you think you are pregnant or planning to become pregnant or you are not using any contraceptive method.
- You are sensitive (allergic) to the active ingredient or to any one of the additional ingredients that this medicine contains or to other medicines of this group such as amlodipine, nifedipine, felodipine, isradipine, nifedipine or lacidipine.
- You suffer from certain heart diseases: uncontrolled heart failure, obstruction of the blood flow from the heart, unstable angina (angina at rest or progressively increasing) within one month of a heart attack.
- You suffer from severe liver or kidney disease.
- You are concomitantly taking: ciclosporin, antifungals medicine such as ketoconazole or itraconazole, antibiotics of the macrolide family such as erythromycin or troleandomycin, antiviral medicines such as ritonavir.
- You eat grapefruits or drink grapefruit juice.

**Special warnings regarding the use of this medicine:**

- **Before using Vasodip tell your physician if:**
  - You suffer from liver or kidney problem, or are in dialysis.
  - You suffer from other certain heart problem, that were not treated by inserting a pacemaker or if you suffer from angina.
  - You have been told in the past by your

physician that you have intolerance to certain sugars.

- You are sensitive to any type of food or medicine.

**Tell the physician or pharmacist if you are taking or have recently taken other medicines, including non-prescription drugs and nutrition supplements.** Especially inform the physician or pharmacist if you are taking:

- Other antihypertensive such as  $\beta$  blockers (e.g metoprolol), diuretics or ACE inhibitors
- quinidine or anidaronone (for fast heartbeat)
- phenytoin or carbamazepine (for epilepsy), your physician may monitor your blood pressure values at a higher frequency than usual
- rifampicin (for tuberculosis)
- cimetidine (for stomach ulcers, indigestion and heartburn - more than 800 mg daily)
- midazolam (for sleep induction)
- astemizole or terfenadine (for allergy)
- digoxin (for the treatment of heart problems)
- simvastatin (to reduce cholesterol)

See also section 2 "Do not use this medicine if".

#### Use of this medicine and food

Consuming grapefruit or grapefruit juice may increase the effect of **Vasodip** and therefore should be avoided during the treatment period.

#### Use of this medicine and alcohol consumption

Avoid consuming alcohol beverages while taking **Vasodip** as alcohol may increase the effect of **Vasodip**.

#### Pregnancy and breastfeeding

Do not use the medicine if you are pregnant or breastfeeding, you think you are pregnant or planning to become pregnant or you are not using any contraceptive method.

#### Driving and using machines

The use of this medicine may cause dizziness, weakness and tiredness, therefore make sure that it does not have such an effect on you before performing activities such as driving or operating machinery.

#### Important information about some of the ingredients of this medicine

This medicine contains lactose, if you have been told in the past by your physician that you have intolerance to certain sugars, consult a physician before starting the treatment with this medicine.

### 3. How to use this medicine?

Always use according to the physician's instructions. Check with the physician or

the pharmacist if you are not sure.

The dosage and administration will be determined by the physician only. The usually recommended dosage is: one tablet daily at the same time.

**Do not exceed the physician's recommended dose.** May be halved. Swallow the tablet with a small amount of water, preferably in the morning, at least 15 minutes before breakfast. There is no information about crushing/chewing

The medicine is not intended for children under 18 years of age.

#### Tests and follow up

During the treatment with this medicine blood pressure, ECG and heart rate tests should be performed.

**If you have accidentally taken a higher dosage than you should,** the following effects may occur: an excessive reduction in blood pressure, irregular or rapid heart rate, loss of consciousness. If you have taken an overdose or if a child accidentally swallowed the medicine, proceed immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

**If you forget to take the medicine** at the specified time, skip the forgotten dose and use the next dose as scheduled. Do not take a double dose.

Continue with the treatment as recommended by the physician.

Even if there is an improvement in your health, do not discontinue the treatment with this medicine without consulting the physician or pharmacist.

If you discontinue the treatment with the medicine your blood pressure may increase again

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

If you have any further questions regarding the use of this medicine, consult a physician or pharmacist.

#### 4. Side Effects

Like all medicine, the use of **Vasodip** may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

**Refer to your physician immediately in case of:**

- Rare side effects (appear in 1 to 10 users out of 10,000): Angina pectoris (chest pain due to deficient blood supply to the heart).
- Very rare side effects (appear in less than 1 users out of 10,000): Blood pressure drop, chest pain, fainting and allergic reaction (symptoms such as:

itching, rash, or hives may appear).

Patients with pre-existing angina pectoris may experience an increase in the frequency, duration or severity of the attacks due to the use of medicines from this group. Isolated cases of heart attack may occur.

#### Additional side effects

- Uncommon side effects (appear in 1 to 10 users out of 1000): headache, dizziness, faster heart beats, palpitations (heart pounding or racing), sudden redness of the face, neck or chest, ankle swelling.
- Rare side effects: digestive system disorders which include digestive difficulties, heartburn, diarrhea, nausea, vomiting and abdominal pain, sleepiness, weakness, tiredness, rash, passage of large amount of urine, muscle pain.
- Very rare side effects: swelling of the gums, changes in liver function (detected by laboratory tests), increased in the frequency of urination.

If a side effect appears, or if any of the side effects worsens, if you suffer from side effects not mentioned in the leaflet, or if there is a change in your general feeling, consult your physician.

Side effects can be reported to the Ministry of Health by clicking on the link [www.health.gov.il](http://www.health.gov.il) or to a hospital emergency room and bring the package of the medicine with you. [www.health.gov.il](http://www.health.gov.il) directing to the online form of adverse events reporting or via the following link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

#### 5. How to store the medicine?

- Avoid poisoning! This medicine and all other medicine should be stored in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed by your physician.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Do not store at the temperature above 25°C. Store in the original package.

#### 6. Additional information

In addition to the active ingredients, this medicine also contains: microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, povidone, hypromellose, magnesium stearate, titanium dioxide, macrogol 6000, talc, ferric oxide.

- Each tablet of **Vasodip 10** contains approximately 29 mg lactose.

- Each tablet of **Vasodip 20** contains approximately 57 mg lactose.

#### What does the medicine look like and contents of the package:

**Vasodip 10 mg:** yellow, round, film-coated tablets with a scored line on one side. Approved pack sizes: 7, 10, 14, 20, 28, 30, 50, 100.

**Vasodip 20 mg:** pink, round, film-coated tablets with a scored line on one side. Approved pack sizes: 7, 10, 14, 28, 30, 35, 42, 50, 56, 98, 100. Not all pack sizes may be marketed.

This leaflet was checked and approved by the Ministry of Health on: 01.2016

**Medicine registration number at the National medicines registry of the Ministry of Health:**

**Vasodip 10 mg, tablets:** 109 87 29303  
**Vasodip 20 mg, tablets:** 130 24 30881

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Registration holder:

**Dexcel® Ltd.**

1 Dexcel St., Or-Akiva 3060000, Israel