Patient package insert according to the Pharmacists' Regulations (Preparations)-1986
This medicine can be sold with a physician's prescription only

VASODIP® 10, Tablets

Each tablet contains Lercanidipine hydrochloride 10 mg
Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems that their medical condition is the same as yours.

1. What is the medicine intended for?

For the treatment of mild to moderate high blood pressure.
Therapeutic group: calcium channel blockers of the dihydropyridine derivative.

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (Lercanidipine hydrochloride) or to any of the other ingredients this medicine contains (see section 6).
- You suffer from certain heart diseases:
  - obstruction of the blood flow from the heart
  - untreated heart failure
  - unstable angina (angina at rest or progressively increasing)
  - within one month of a heart attack
- You suffer from severe liver problems
- You suffer from severe kidney problems
- You are concomitantly taking medicines that are inhibitors of hepatic metabolism, such as:
  - antifungal medicines (such as ketoconazole or itraconazole)
  - antibiotics of the macrolide group (such as erythromycin, troleandomycin or clarithromycin)
  - antiviral medicines (such as ritonavir)
- You are taking another medicine called ciclosporin (used after transplants to prevent organ rejection)
- You consume grapefruits or grapefruit juice.

Special warnings regarding the use of the medicine:
Before the treatment with Vasodip, tell the doctor if:

- You suffer from a heart problem
- You suffer from liver or kidney problems

You must tell your doctor if you think you are pregnant (or might become pregnant) or breastfeeding (see “Pregnancy and breastfeeding” section).

Children and adolescents
The safety and efficacy of this medicine in children aged up to 18 years have not been established.

Drug interactions
If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutrition supplements, tell the doctor or pharmacist. This is because when **Vasodip** is taken with other medicines its effect or effect of the other medicine may be changed or certain side effects may occur more frequently (see also in section 2 “Do not take this medicine if”).
Especially tell the doctor or pharmacist if you are taking:
- phenytoin, phenobarbital or carbamazepine (to treat epilepsy)
- rifampicin (to treat tuberculosis)
- astemizole or terfenadine (to treat allergies)
- amiodarone, quinidine or sotalol (to treat a fast heartbeat)
- midazolam (for sleep induction)
- digoxin (to treat heart problems)
- beta-blockers e.g., metoprolol (a medicine to treat high blood pressure, heart failure and abnormal heart rhythm)
- cimetidine (more than 800 mg daily, a medicine to treat stomach ulcers, indigestion and heartburn)
- simvastatin (to reduce cholesterol)
- other medicines to treat high blood pressure

Use of the medicine and food
- A high fat meal significantly increases blood levels of the medicine (see section 3 “How to use the medicine”).
- Do not take **Vasodip** with grapefruit or grapefruit juice (they can increase its hypotensive effect). See in section 2 “Do not use the medicine if”.

Use of the medicine and alcohol consumption
Alcohol may increase the effect of **Vasodip.** Do not consume alcohol during treatment with the medicine.

Pregnancy and breastfeeding
Vasodip is not recommended if you are pregnant. Do not use the medicine during breastfeeding. There are no data about use of **Vasodip** in pregnant or nursing women. If you are pregnant or breastfeeding, if you are not using any contraceptive methods, if you think you are pregnant or planning to become pregnant, consult a doctor or pharmacist before using this medicine.

Driving and using machines
If you feel dizziness, weakness or drowsiness during treatment with the medicine, do not drive or operate machines.

Important information about some of the ingredients of the medicine
This medicine contains lactose. If you have been told in the past by the doctor that you have intolerance to some sugars, consult a doctor before starting treatment with this medicine.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to use this medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or the pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.
The dosage and manner of treatment will be determined by the doctor only.

Adults: The usual recommended dosage is: one tablet once daily at the same time each day. Swallow the tablet with some water, preferably in the morning, at least 15 minutes before breakfast (see in section 2 “Use of the medicine and food”). The doctor may advise to increase the dose up to 20 mg daily, if needed.
Do not exceed the recommended dose.

The tablets may be halved**.** There is no information about crushing/chewing.

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

Elderly patients: No adjustment of the daily dose is required. However, special care should be exercised in starting treatment.

Patients suffering from liver or kidney problems: special care is needed in starting treatment in these patients and an increase in daily dose to 20 mg should be approached with caution. See also in the section 2 “Do not use the medicine if”.

If you have accidentally taken a higher dosage
If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you. Taking more than recommended dosage of the medicine may cause an excessive decrease in blood pressure and irregular or rapid heart rate.

If you forget to take the medicine
If you forgot to take this medicine at the designated time, do not take a double dose. Take the next dose at the regular time and consult a doctor.

Continue with the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop taking this medicine without consulting the doctor.

If you stop taking the medicine
If you stop taking 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 further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side Effects

Like any medicine, the use of **Vasodip** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
The following side effects may occur with this medicine:

Some side effects can be serious.
Refer to a doctor immediately with the occurrence of:
Rare side effects (effects that occur in 1-10 out of 10,000 users): angina pectoris (chest pain due to lack of blood supply to the heart), allergic reactions (symptoms include itching, rash, urticaria), fainting.

Patients with pre-existing angina pectoris may experience an increased frequency, duration or severity of the attacks with the medicine group, that **Vasodip** belongs to. Isolated cases of heart attack have been observed.

Additional side effects
Common side effects (effects that occur in 1-10 out of 100 users): headache, fast heart rate, feeling a fast or irregular pulse (palpitations), sudden reddening of the face, neck or upper chest (flushing), ankles swelling.

Uncommon side effects (effects that occur in 1-10 out of 1,000 users): dizziness, drop in blood pressure, heartburn, nausea, stomach pain, skin rash, itching, muscle pain, passage of large amounts of urine, feeling weak or tired.

Rare side effects (effects that occur in 1-10 out of 10,000 users): sleepiness, vomiting, diarrhea, hives, increase in frequency of urination, chest pain**.**

Side effects with unknown frequency (effects for which a frequency has not yet been determined): swelling of the gums, changes in liver function (detected in blood tests), cloudy fluid (when performing dialysis through a tube into your abdomen), swelling of face, lip, tongue or throat, which may cause difficulty in breathing or swallowing.

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

Side effects can be reported to the Ministry of Health by clicking the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants 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 (תאריך התפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, povidone, hypromellose, magnesium stearate, titanium dioxide (E171), macrogol 6000, talc, ferric oxide (E172).

What the medicine looks like and what the package contents:
Yellow, round, biconvex, film-coated tablets with a scored line on one side. Approved package sizes: 10, 30 tablets. Not all package sizes may be marketed.

Revised in December 2022 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health: 109 87 29303 05

Manufacturer and registration holder: Dexcel Ltd. 1 Dexcel St., Or Akiva 3060000, Israel