Patient package insert according to Pharmacists' Regulations (Preparations), 1986.

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

Verapress® 240 SR - Sustained release caplets

Each caplet contains Verapamil hydrochloride 240 mg.

For list of inactive ingredients, please see section 6 "Additional information"

Read this entire leaflet carefully before you start using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their illness is similar.

Do not take this medicine with the grapefruit juice (See also section "Use of this medicine and food").

This medicine is not intended for children and adolescents.

1. What is the medicine intended for?

For the treatment of hypertension and angina pectoris.

Therapeutic group: Calcium channel blocker.

2. Before using the medicine:

Do not use the medicine if:

- you are breastfeeding.
- you are hypersensitive (allergic) to the active ingredient (verapamil) or to any of the additional ingredients that this medicine contains, listed in section 6.
- you suffer from heart problems, such as: low blood pressure (systolic below 90 mmHg) or very low blood pressure (for example, in case of shock – sudden and fast decrease of blood pressure); heart attack or recent heart attack, especially if slow heartbeat, low blood pressure or left ventricle failure are involved; severe bradycardia (slow heartbeat, less than 50 beats per minute); heart failure; atrial flutter or fibrillation accompanied by an accessory conduction pathway [for instance, Wolff-Parkinson-White syndrome (a heart problem causing rapid heart rate sometimes associated with symptoms such as dizziness or faintness) or Lown-Ganong-Levine syndrome].
- you do not have a pacemaker and notified by your doctor that you suffer from second or third degree heart block or sick sinus syndrome (slow heart beat accompanied sometimes by episodes of fast heart beat or a blockage in the conduction of electrical impulses).
- you are treated with a beta-blocker (a certain type of cardiovascular medicine) via injections (except in intensive care).

Consult your physician or pharmacist before taking the medicine if you are unsure.

Special warnings regarding the use of this medicine:

- **Before treatment with Verapress 240 SR tell the physician if:**
  - you suffer, or have suffered in the past, from impaired function of the heart and/or vascular system (see section 2 above), the liver or kidney/urinary tract.
  - you suffer from a disease affecting the nervous system such as muscular atrophy, muscle weakness (e.g. myasthenia gravis, Lambert-Eaton syndrome, advanced Duchenne muscular atrophy).
  - you are pregnant or planning to become pregnant (see also section "Pregnancy and breastfeeding").
  - you are planning to have medical or dental surgery. Verapress SR 240 may affect the anaesthetics or other treatments used.
  - you are sensitive to any food or drug.

If you are unsure whether these conditions apply to you, consult your doctor or pharmacist.

If you are taking or have recently taken any other medicines, including non prescription drugs and nutrition supplements, tell your physician or pharmacist. Especially you should inform the physician or the pharmacist if you are taking medicines from following groups or if you have just completed treatment with the following medicines:

- Aspirin, anticoagulants (to prevent blood clots).
- Medicines for treating high blood pressure including diuretics, beta-blockers (e.g. propranolol, metoprolol, atenolol) or alpha-blockers (e.g. terazosin or prazosin).
- Medicines for treating heart disease, e.g. flecainide, quinidine, disopyramide, nitrates, digitalis, digoxin (see section "Tests and follow up"), digitoxin or amiodarone.
- Theophylline (for treating asthma).
- Carbamazepine, phenytoin, phenobarbital (for treating epilepsy).
- Mood-altering drugs or for sedation such as: imipramine, lithium, buspirone or midazolam.
- Drugs for treating diabetes such as glibenclamide.
- Drugs for treating infectious diseases such as: erythromycin, clarithromycin, telithromycin or rifampicin.
- Drugs for treating cancer such as: doxorubicin.
- Medicines for treating indigestion, ulcer and heartburn such as cimetidine.
- Drugs for treating gout such as colchicines, sulfinpyrazone.
- Drugs for preventing transplant rejection such as: ciclosporine, sirolimus, tacrolimus or everolimus.
- Drugs for reducing blood cholesterol such as: atorvastatin, simvastatin, or lovastatin (other drugs from this family – fluvastatin, pravastatin and rosuvastatin do not cause drug interactions with verapamil). Simultaneously taking simvastatin in high daily doses and verapamil increases the risk of muscles disorders or a breakdown of muscle cells (myopathy/rhabdomyolysis). Therefore simultaneous treatment requires regular medical check-up.
- Medicines for treating migraine such as almotriptan.
- Drugs for treating AIDS or HIV (such as ritonavir, indinavir).
- Medicines used during surgery (anesthetic gas) or for relaxing muscles.
- Plant Hypericum (St. John's Wort) and grapefruit juice.
- Medicines for treating fungal disease (e.g. clotrimazole, ketoconazole).

The above mentioned list of medicines that could cause drug interactions with **Verapress 240 SR** is not final. Consult your doctor or pharmacist before using any medicine.

Use of this medicine and food:
Take **Verapress 240 SR** during a meal and with a glass of water to help swallow the tablet. Do not consume grapefruits and do not drink grapefruit juice whilst using the medicine.

Use of this medicine and alcchol consumption:
Do not drink wine or other alcoholic beverages during the period of treatment with this medicine. **Verapress 240 SR** delays alcohol's breakdown and increases alcohol concentration in the blood and the effect of alcohol.

Pregnancy and breastfeeding:
If you are pregnant or are planning to become pregnant, consult your physician. Verapamil (the active ingredient in the medicine) may pass from your blood system to the fetus. The doctor may monitor your condition closely.
Do not use this medicine if you are breastfeeding (see section 2). The active ingredient of the medicine passes into the breast milk. Individual cases of increase in prolactin secretion and spontaneous lactation have been reported.

Driving and use of machinery:
Use of this medicine may cause headache, dizziness or tiredness and as a result impair alertness and the ability to react and therefore special care is required. Do not drive, operate dangerous machinery or engage in any other activity which requires alertness, until you know how the medicine affect you.

Important information about some of the ingredients of the medicine:
Each caplet contains about 35 mg sodium. To be taken into consideration by patients on a controlled sodium diet.

Use in children:
This medicine is not intended for use in children and adolescents.

3. How to use this medicine

Always use according to your physician's instructions. Check with your physician or pharmacist if you are unsure. The dosage and administration will be determined by the physician only.
The medicine should be taken at regular intervals as determined by the attending physician.
Do not exceed the recommended dose.

Directions for use:
Do not chew/crush the caplet!
The caplet can be halved.
Take the medicine with a glass of water, with the meal. Do not take the medicine while lying down.

Tests and follow up:

- During treatment with the medicine blood pressure measurements, ECG, heart rate and liver function tests should be performed.
- Treating high blood pressure with this medicinal product requires regular medical check-ups.
- The physician may follow your condition closely if: you suffer, or have suffered in the past from low blood pressure, heart failure, slow or irregular heart beat in unusual manner, any heart problem, if you suffer, or have suffered in the past from kidney or liver problems.
- During concomitant usage of **Verapress 240 SR** with digoxin, the digoxin concentration in the blood might be increased, for this reason, precautionary measures should be taken to check for symptoms of a digoxin overdose and, if necessary, the doctor will change the digoxin dose.

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a physician or a hospital emergency room and bring the package of the medicine.
If you have taken an overdose, you might suffer from the following symptoms:
severe drop in blood pressure, cardiac insufficiency, abnormal heart rate which can lead to cardiovascular shock and cardiac arrest, loss of consciousness or coma, increased blood sugar, decrease of potassium blood level, decrease of the pH value in the blood (metabolic acidosis), oxygen deficiency in the body tissue (hypoxia), cardiovascular shock with water accumulation in the lungs (pulmonary edema), impairment of the kidney function and convulsions. Cases of death are uncommon.

If you forgot to take this medicine at the specified time, take it as soon as you remember, unless it is almost time for your next dose. In this case take your next dose at the regular time and consult with your doctor. Never take a double dose in the same day.
Continue with the treatment as recommended by the physician. Even if there is an improvement in your health, do not stop treatment with this medicine without consulting your physician.

If you stop taking the medicine, your condition may get worse. Untreated hypertension can lead to severe consequences. According to the decision of your physician, discontinuation of the treatment should be done gradually.
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 your physician or pharmacist.

4. Side effects:

Like any medicines, the use of **Verapress 240 SR** can cause side effects, in some users. Do not be alarmed while reading the side effects. You may not suffer from any of them.

Stop using the medicine and refer immediately to the physician if you experience the following side effects:

- severe allergic reaction including wheezing or unexpected difficulty in breathing, swelling of the face with itching, swelling of the eyelids, throat, tongue, mouth, lips; pruritis, skin rash or severe skin rush with blistering and peeling of the skin or high fever with red blotches on the skin, joint pain and/or eye inflammation.
- dizziness or fainting due to low blood pressure.
- allergic reaction that includes urticaria (itchy or painful rash).

Refer to your physician immediately if you experience the following side effects:

- yellowing of the skin or eyes, a fever or tenderness around the middle or if you have elevated levels of liver enzymes (signs that your liver may not be functioning as well as usual).
- bradycardia (slow heart beats); irregular heart beat; palpitations (awareness of an irregular or rapid heart beat); rapid heart beat (tachycardia); swollen ankles and limbs (signs of cardiac insufficiency); reversible impairment of liver function; chest pain for the first time or chest pain that become more frequent; dizziness; weakness; confusion or a burning sensation in the feet, which may become hot and throbbing.
- low blood pressure.

Additional side effects:

Very common side effects (effects that appear in more than one in ten users): constipation, nausea, feeling of fullness.

Common side effects (effects that appear in 1 to 10 users out of 100):

- Headache; dizziness; slow heart beat; low blood pressure; redness; swelling of body, hands or feet; occurrence of a cardiac insufficiency or exacerbation of an existing cardiac insufficiency; severe drop in blood pressure and/or when changing your posture from lying or sitting to standing; restlessness; tiredness; cardiac conduction disorders in the heart (first degree heart block); drowsiness; 'pins and needles' and a cold feeling in the extremities; trembling (tremor); erythromelalgia (painful reddening and swelling of the extremities).

Uncommon side effects (effects that appear in 1 to 10 users out of 1000):

- Beating of the heart (palpitations) or fast heart rate.
- Abdominal pain.
- Itching or tingling.
- Vomiting.
- Obstruction of the intestine.
- Ringing or buzzing in the ears (tinnitus).
- Spasms in the bronchial muscles (breathing problems).
- Extra growth of the gums. Rare effect that resolves upon stopping the treatment.
- Severe cardiac conduction disorders in the heart (second or third degree heart block).
- Reduced glucose tolerance.
- Liver inflammation (hepatitis), probably caused by an allergic reaction (with increase of liver-specific enzymes: regresses after discontinuing treatment with the medicine).
- Impotence.

Rare side effects (in 1 to 10 users out of 10,000):

- Numbness or tingling.
- Excessive sweating.
- Purpura.
- Muscle weakness, muscle pain, painful joints.
- Development of breasts in male, milk production that causes leaking from the breasts in males and females.

Very rare side effects (in less than one user out of 10,000):

- Exacerbation of certain muscle diseases (myasthenia gravis, Lambert–Eaton syndrome, advanced Duchenne muscular dystrophy).
- Abnormal skin reaction to sun.
- Cardiac arrest.
- Increase of prolactin hormone in the blood.
- Effects associated with the nervous system (extrapiramidal) such as movement disorders.

Side effects with unknown frequency (effects that their frequency has not been determined yet):

- Hypersensitivity.
- Severe dizziness (vertigo).
- Heart rate problems.
- Abdominal discomfort.
- Bumps and blisters.
- Hair loss.
- Rash.
- Urticaria (itchy painful rash).
- Excessive push for skin rubbing and scratching.
- Paralysis.

If a side effect appears, if one of the side effects worsens, or when you suffer from a side effect not mentioned in this leaflet, consult your physician.

Side effects can be reported to the Ministry of Health using the link "דיווח על תופעות לוואי עקב טיפול תרופתי" on the homepage of Ministry of Health official site (www.health.gov.il) which refers to an online form for adverse reactions reporting, or via below 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 medicines, must 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 a physician!
- Do not use after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.

Storage conditions: Do not store above 25ºC temperature. Store in the original package.

6. Additional information

In addition to the active ingredient, this medicine also contains inactive ingredients:
Sodium alginate, microcrystalline cellulose, povidone, hypromellose 2208, hypromellose 2910, titanium dioxide E171, silica colloidal anhydrous, magnesium stearate, macrogol 400, quinoline yellow aluminium lake E104, indigo carmine aluminium lake E132, carnauba wax.

What the medicine looks like and content of package:
Light-green film-coated caplet with a score line on both sides.
Approved pack sizes: 10, 28, 30, 100. Not all package sizes may be marketed.

Drug registration number at the national medicines registry of the Ministry of Health: 068-63-26427-00.

This leaflet was checked and approved by the Ministry of Health in 3/2016.

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Manufacturer and registration holder:

Dexcel® Ltd

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