

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

Verapress® 240 SR, sustained release caplets

Each caplet contains: Verapamil hydrochloride 240 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 this 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 you think that their medical condition is the same as yours.

1. What is the medicine intended for?

For the treatment of mild to moderate hypertension. For the treatment and prevention of angina pectoris.

Therapeutic group: Calcium channel blocker.

Calcium channel blockers change the amount of calcium entering the muscle cells in your heart and blood vessels. This can change the strength and speed with which your heart beats. It also opens up the blood vessels so blood can flow through the body more easily. This helps more oxygen to get to your heart muscle and can lower your blood pressure.

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (verapamil hydrochloride) or to any of the other ingredients the medicine contains (see section 6).
- You suffer from a heart shock (cardiogenic shock – a dangerous decrease in blood flow)
- You have recently had a heart attack with a complication of a slow heart beat
- You have very low blood pressure or left ventricle failure
- You do not have a functioning pacemaker and you suffer from second or third degree heart block or sick sinus syndrome
- You have a sino-atrial block
- You have heart failure
- You have a slow heart beat (under 50 beats per minute)
- You have low blood pressure [the high value (systolic) is below 90 mmHg]
- You have an atrial flutter or fibrillation accompanied by an extra electrical pathway (such as Wolff-Parkinson-White syndrome)
- You take ivabradine (for heart conditions)

Special warnings regarding the use of the medicine Before the treatment with Verapress 240 SR, tell the doctor if:

- You are pregnant, planning to become pregnant or

breastfeeding.

- You have an abnormally slow or irregular heart beat.
- You have recently suffered from a heart attack.
- You have liver or kidney problems.
- You have or have had heart problems.
- You suffer from an illness where there is damage to the nerve to muscle transmission such as myasthenia gravis, Lambert-Eaton syndrome, advanced Duchenne muscular dystrophy.

Drug interactions

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

- Beta-blockers used to treat high blood pressure and heart conditions (such as atenolol, propranolol, and metoprolol)
- Alpha blockers used to treat high blood pressure and heart conditions (such as prazosin, and terazosin)
- Diuretics
- Medicines known as statins such as atorvastatin, lovastatin, simvastatin, used to lower cholesterol levels
- Any other medicine for the treatment of high blood pressure or an abnormal heart beat (arrhythmia) such as quinidine, flecainide, disopyramide, digoxin, and digitoxin
- Dabigatran (a medicine to prevent the formation of blood clots)
- Medicines containing ivabradine for the treatment of certain heart diseases (see also in section 2 "Do not use the medicine if")
- Medicines used to treat depression (including the herbal product St John's Wort), anxiety or psychosis. These may include imipramine, buspirone, and lithium.
- Medicines known as immunosuppressants such as ciclosporin, sirolimus, everolimus and tacrolimus. These are used to prevent organ transplant rejection
- Glibenclamide, used to treat certain types of diabetes
- Aspirin, a non-steroidal anti-inflammatory painkiller (NSAID) used to relieve pain and reduce fever
- Almotriptan, used to treat migraine
- Midazolam, used as a sedative or anaesthetic
- Theophylline, used to treat asthma
- Doxorubicin, an anti-cancer medicine
- Cimetidine, used to treat indigestion or stomach ulcers
- Rifampicin, used to treat tuberculosis and other types of infection
- Carbamazepine, phenytoin or phenobarbital (phenobarbitone). These medicines are used as anti-convulsants
- Ritonavir, used to treat HIV
- Erythromycin, clarithromycin and telithromycin, used to

treat certain types of infection

- Colchicine or sulfapyrazone, used to treat gout

Tell the surgeon or dentist that you are taking **Verapress 240 SR** if surgery is planned, as it may affect the anaesthetic used.

Use of this medicine and food

Take **Verapress 240 SR** with a meal. Do not drink grapefruit juice while using the medicine as it may affect the absorption. This does not occur with other fruit juices such as orange, apple or tomato juice.

Use of this medicine and alcohol consumption

Verapress 240 SR increases the time your body takes to get rid of alcohol. This means that a smaller amount of alcohol will raise the blood alcohol level above the permitted level to drive. It will also take you longer to sober up.

Pregnancy, breastfeeding and fertility

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

Driving and using machines

Do not drive, operate machinery, or do anything that requires you to be alert, until you know how the medicine affects you.

Verapress 240 SR may cause dizziness in some people, especially at the start of the treatment.

Important information about some of the ingredients of this medicine

Each caplet contains about 35 mg sodium (a main ingredient in cooking/table salt). This is equivalent to 1.75% of the maximum recommended daily intake of sodium for an adult.

3. How to use this medicine

Always use this medicine according to the doctor's instructions. Check with the doctor or 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.

Do not exceed the recommended dose.

Children: Verapress 240 SR is not intended for children.

Method of administration:

Swallow the medicine with a glass of water, with the meal. The caplet can be halved. If halving the caplet, discard the half of the caplet not intended for immediate use. Do not chew/crush the caplet as it is a sustained release medicine.

If you have accidentally taken a higher dose

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.

If you forgot to take the medicine

If you forgot to take this medicine at the designated time, take a dose as soon as you remember, unless it is almost time for the next dose. In this case, skip the forgotten dose. Do not take a double dose to make up for the forgotten dose.

Continue with the treatment as recommended by the doctor.

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

If you stop taking the medicine

If you stop taking the medicine, your condition may worsen.

Do not take medicines in the dark! Check the label and the dose each time you take a 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 **Verapress 240 SR** 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.

Refer to the doctor immediately with the appearance of the following side effects:

- Yellowing of the skin or eyes, a fever or tenderness around the stomach. These are signs of impaired liver function.
- Palpitations (awareness of the heart beats), chest pain for the first time or chest pain becoming more frequent, swollen ankles, sensation of heat and pain in the hands or feet.
- Swelling of the limbs
- Wheezing, difficulty breathing, swelling of the mouth, lips or tongue or severe skin rash, appearing unexpectedly

The most common side effect is constipation.

Other side effects include: abnormal heart beat, flushing of the face or neck, headaches, feeling or being sick, abdominal pain or discomfort, dizziness, vertigo, ringing or buzzing in the ears (tinnitus), tiredness, tremor, movement disorders, muscle weakness, aches and pain in the joints and/or muscles, skin rash or itching, a tingling or prickling feeling on the skin, numbness and hair loss. Impotence may occur rarely.

Other side effects might occur if **Verapress 240 SR** is taken for a long time. **Tell the doctor** if you develop swollen gums which starts to spread over the teeth, swelling of the breasts (males), milk production (males and females). These effects are rare and are resolved upon stopping treatment.

If a side effect appears, 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 via the link "דיווח על תופעות לוואי עקב טיפול תרופתי" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following 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 פגוה) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: Do not store above 25°C. Store the caplets in the original blister pack as the product is sensitive to moisture. If halving a caplet, discard the half of the caplet not intended for immediate use.
- 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:

Sodium alginate, microcrystalline cellulose, povidone, hypromellose, titanium dioxide (E171), silica colloidal anhydrous, magnesium stearate, macrogol, quinoline yellow aluminum lake (E104), indigo carmine aluminum lake (E132), carnauba wax.

What the medicine looks like and what the package contains:

Light green caplet with a score line on both sides.

Approved package sizes: 10, 30 caplets. Not all package sizes may be marketed.

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

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Manufacturer and registration holder: **Dexcel® Ltd.**

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