

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

**Cordamil 40 mg
Cordamil 80 mg
Film-coated tablets**

Active ingredient

Cordamil 40 mg: Each tablet contains 40 mg verapamil hydrochloride

Cordamil 80 mg: Each tablet contains 80 mg verapamil hydrochloride

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your 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 to you that their medical condition is similar to yours.

1. What is this medicine intended for?

1. Cordamil is used for treatment of coronary heart disease, including:
 - chronic stable angina pectoris (effort angina);
 - unstable angina pectoris:
 - aggravated angina, resting angina, vasospastic angina (Prinzmetal angina adrenergic);
 - post-heart attack angina in patients without heart failure, when beta-blockers are contraindicated;
2. Prevention of ventricular fast heart rate disorders not controlled by Cardiac glycosides with cardiotonic effector beta-blockers (for example supraventricular paroxysmal tachycardia, atrial fibrillation/flutter with rapid ventricular response, except for Wolff-Parkinson-White syndrome).
3. Treatment of moderate to mild blood pressure.

Therapeutic group: selective calcium channel blockers, calcium blockers with direct cardiac effects, phenylalkylamines.

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredients or to any of the other ingredients in this medicine (listed in section 6).
- you have cardiogenic shock.
- you had an acute myocardial infarction with complications such as a slower heartbeat (bradycardia), marked hypotension or reduced heart function on left side (left-sided heart failure).
- you have second- or third-degree AV block (severe conduction problems in the heart between upper and lower chambers of the heart), unless you have a functional pacemaker.
- you have sinus node disease (a heart rhythm disorder caused by sinus node dysfunction), unless you have a functional pacemaker.
- bradycardia with a frequency <50 beats per minute.
- you have heart failure (the heart is not able to pump blood).
- Low blood pressure (systolic blood pressure <90 mmHg).
- You have Atrial fibrillation/atrial flutter (heart rhythm disorders caused by abnormal stimulation in the upper chambers), associated with Wolff-Parkinson-White syndrome (sudden onset of rapid heartbeat caused by sudden increased pulse flow between the upper chambers and slower heart rate due to the presence of an additional conduction system): there is an increased risk that you will have ventricular tachycardia (rapid heartbeat in the lower chambers [ventricles]).

Do not administer intravenous beta-blockers to patients receiving Cordamil (except those in intensive care units) (see also: 'Drug interactions').

Special warnings about using this medicine

Before treatment with Cordamil, tell your doctor:

- if you have first-degree AV block (mild conduction problems of the heart, between the upper and lower chambers);
- if you have low blood pressure (systolic blood pressure below 90 mmHg);
- if your resting heart rate is below 50 beats per minute (bradycardia);
- if you have liver failure (see 'How to use Cordamil');
- if you have diseases that affect neuromuscular transmission (myasthenia gravis, Lambert-Eaton syndrome, progressive Duchenne muscular dystrophy).

You should visit your doctor regularly for treatment with Cordamil so that they will be able to evaluate your health.

Children and adolescents

The medicine is intended for use in adolescents from the age of 14 who weigh over 50 kg and children aged 6-14, for treatment of heart rhythm disorders only.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. The effect of the following medicines may change if taken at the same time as Cordamil.

Medicines used to treat heart rhythm disorders, beta-blockers (propranolol, metoprolol)

Verapamil increases the cardiovascular effects of these medicines.

Do not administer intravenous beta-blockers to patients using Cordamil (except in intensive care units) (see also section 2: 'Do not use this medicine if').

Inhalation anesthetics

When inhalation anesthetics are taken together with verapamil hydrochloride, they should be titrated carefully to prevent additional effects on the cardiovascular system (such as AV block, slow heart rate, low blood pressure, heart failure).

Medicines used to lower blood pressure, diuretics, medicines used to dilate the blood vessels

The blood pressure-lowering effect may increase.

Digoxin (used to reduce heart contractions)

Increased digoxin levels in the blood, caused by reduced secretion of the medicine through the kidneys. As a precaution, you should pay attention to signs of digoxin overdose and, if necessary, your doctor will change (reduce) your dosage of digoxin (possibly after determining the amount of digoxin in your blood).

Quinidine, flecainide (used to treat heart rhythm disorders)

Concurrent use may lead to low blood pressure and pulmonary edema (fluid in the lungs) in patients with a certain heart condition (hypertrophic obstructive cardiomyopathy). Cordamil increases quinidine levels in the blood.

Carbamazepine (used to treat seizures)

Verapamil increases the level of carbamazepine in the blood. This may increase the side effects of carbamazepine such as double vision, headache, ataxia and dizziness.

Lithium (used to treat mania or bipolar disorder)

Verapamil may increase the neurotoxicity of lithium.

Muscle relaxants

Verapamil can increase the effect of these medicines.

Acetylsalicylic acid (used as a pain reliever or to prevent blood clots)

Concurrent use with verapamil leads to an increased tendency to bleed.

Ritonavir (used to treat HIV infections), cimetidine (used to reduce stomach acid secretion)

Concurrent use with verapamil may lead to an increase in the level of verapamil in the blood.

Phenytoin, phenobarbital (used to treat seizures), rifampicin (used to treat tuberculosis), sulfipyrazone (to treat gout)

Combining these medicines with verapamil will lead to low levels of verapamil in the blood and as a result, reduce the effect of verapamil.

Medicines used to reduce cholesterol in the blood (such as lovastatin, atorvastatin), midazolam, buspirone (used to treat anxiety), medicines used to suppress the immune system (cyclosporine, sirolimus, tacrolimus), theophylline (used to treat asthma), glyburide (antidiabetic medicine administered orally), doxorubicin (for treatment of cancer), almotriptan (for treatment of migraines).

Combining these medicines with verapamil may lead to an increase in the levels of these medicines in the blood.

Terazosin, prazosin (for treatment of benign prostatic hypertrophy or high blood pressure)

Concurrent use with verapamil increases the blood pressure-lowering effect.

Antibiotics (erythromycin, telithromycin)

Concurrent use with verapamil may lead to an increase in the level of verapamil in the blood.

Simvastatin (used to lower blood lipid levels)

When using verapamil in combination with high doses of simvastatin, there is an increased risk of myopathy (a disorder of the striated muscles (skeletal muscles)) or rhabdomyolysis (destruction of muscle tissue cells). The dose of simvastatin should be adjusted according to your doctor's instructions.

Hypericum perforatum (to treat depression)

Concurrent use leads to lower levels of verapamil in the blood.

Therefore, do not use Cordamil in combination with any of the medicines mentioned above, unless your doctor advised you to do so.

Using this medicine and food

Cordamil should be taken with a meal or immediately after a meal.

Do not eat food or drink beverages containing grapefruit while taking verapamil.

Grapefruit may increase the level of verapamil in your blood.

Using this medicine and alcohol consumption

If you use Cordamil, refrain from drinking alcohol to the extent possible, as verapamil increases the effect of alcohol.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Inform your doctor immediately if you are pregnant, think you may be pregnant or are breastfeeding.

Cordamil should be used during pregnancy only if absolutely necessary.

Cordamil is excreted in breast milk and, therefore, you should stop breastfeeding during treatment with Cordamil.

Driving and using machines

Even when used according to the instructions, Cordamil may affect your ability to react to an extent that impairs your ability to drive, use machines or perform dangerous tasks. This situation occurs especially at the start of treatment, when the dosage is increased, when switching from another treatment to treatment with verapamil, or in combination with alcohol. Do not drive and do not use machines until you know to what extent you are affected by treatment with Cordamil.

Important information about some of this medicine's ingredients

Cordamil contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Cordamil contains tartrazine (E102), which may cause allergic reactions.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The dosage of Cordamil should be adjusted individually according to the severity of the problem.

The recommended dosage is usually:

Adults

The average dose for all indications is 240 mg to 360 mg.

The maximum daily dose should not exceed 480 mg for long-term treatment; in the case of short-term treatment, a higher dose is possible.

Cordamil at a dose of 40 mg is recommended for patients who require low doses (e.g., patients with liver disease and elderly patients).

Adolescents over the age of 14 weighing over 50 kg

Coronary heart disease, paroxysmal supraventricular tachycardia, atrial fibrillation and atrial flutter

The recommended dose is 120-480 mg verapamil hydrochloride, given in 3-4 doses.

Hypertension

The recommended dose is 120-480 mg verapamil hydrochloride, given in 3 doses.

Children aged 6-14 years (only for heart rhythm disorders)

The recommended dose is 80-360 mg verapamil hydrochloride, given in 2-4 doses.

Liver failure

Depending on the severity of the liver damage, the metabolism of verapamil hydrochloride is delayed, which intensifies the effects of the medicine. Therefore, in this group of patients, the dose should be adjusted, and treatment should be started with the minimum effective dose.

Do not exceed the recommended dose.

Method of administration

The tablets should be swallowed whole, with liquid, preferably during or immediately after a meal.

Cordamil 80 mg: The tablet may be split to make it easier to swallow. The two halves of the table should be swallowed. The uniformity of the halves has not been proven.

There is no information about crushing the tablet.

Duration of treatment

There are no restrictions concerning the duration of treatment; this will be determined by your doctor.

If you have the impression that the effect of Cordamil is too strong or too weak, contact your doctor or pharmacist.

Adhere to the treatment as recommended by your doctor.

If you use more Cordamil than you should

If you have accidentally taken a higher dose or if a child has accidentally taken some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. In case of an overdose, you may have the following symptoms: loss of consciousness and even coma, drop in blood pressure, increase or decrease in heart rate, metabolic acidosis.

If you forget to take Cordamil at the scheduled time

Do not take a double dose to make up for a forgotten dose.

Verapamil treatment should not be stopped abruptly and without being instructed to do so by your doctor. Gradual dosage reduction is recommended.

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

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Cordamil may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Side effects of unknown frequency (the frequency of these effects has not been established yet)

- Hypersensitivity reactions;
- Headache;
- Numbness;
- Tremors;
- Extrapyramidal disorders;
- Dizziness, vertigo;
- Ringing in the ears;
- First-, second-, third-degree AV block;
- Sinus bradycardia;
- Heart attack;
- Peripheral edema;
- Palpitations;
- Fast heartbeat;

- Heart failure;
- Low blood pressure;
- Hot flashes;
- Nausea;
- Vomiting;
- Constipation;
- Bowel obstruction;
- Excessive gum growth;
- Abdominal pain/discomfort;
- Swelling of the face, lips, neck;
- Stevens-Johnson syndrome;
- Polymorphic erythema;
- Transient maculopapular erythema;
- Urticaria;
- Purpura;
- Itching;
- Hair loss;
- Muscle weakness;
- Muscle pain;
- Joint pain;
- Impotence;
- Breast enlargement in men;
- Milky breast discharge;
- Fatigue;
- Increased serum liver enzymes;
- Increased level of prolactin in the blood.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package/tray. The expiry date refers to the last day of that month.

Storage conditions

Store below 25°C in the original package.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Additional information

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

Tablet core:

Lactose monohydrate, maize starch, povidone K 30, sodium starch glycolate, talc, magnesium stearate, silica colloidal anhydrous

Tablet coating:

Hypromellose, titanium dioxide (E171), macrogol 6000, talc, tartrazine (E102).

What the medicine looks like and contents of the pack:

Cordamil 40 mg: Convex film-coated light-yellow tablets, with "V 40" engraved on one side.

Cordamil 80 mg: Convex film-coated yellow tablets, with "V 80" engraved on one side and a score line on the other.

The medicine is available in packages of 30 or 60 tablets, packaged in blisters.

Each blister pack contains 10 tablets.

Registration holder's name and address:

Trustpharm Ltd., 50 Hakishon Street, Tel Aviv.

Manufacturer's name and address:

S.C. AC HELCOR S.R.L.

Dr. Victor Babes Street, no. 50, Baia Mare, Romania

This leaflet was revised in April 2022 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:

Cordamil 40 mg: 169-31-36504-99

Cordamil 80 mg: 168-85-36505-99