



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

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

Monocord[®] 25, 40, Tablets
Monocord[®] 50 SR, Slow release tablets

Monocord 20, 40: Each tablet contains Isosorbide mononitrate 20 or 40 mg, respectively.

Monocord 50 SR: Each slow release tablet contains Isosorbide mononitrate 50 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 the 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 you think that their medical condition is similar to yours.

1. What is the medicine intended for?

For the treatment of angina pectoris and prevention of anginal attacks.

Monocord 20, 40 are also used for the treatment of congestive heart failure.

Therapeutic group: Organic nitrates.

Organic nitrates work by widening the blood vessels in the heart to increase the blood supply to the heart. Angina pectoris usually feels like a tight pain in the chest, neck or arm area. The pain comes from the heart muscle and is a sign that part of it is not getting enough oxygen which is necessary for its functioning.

2. Before using the medicine

Do not use the medicine if:

- you are hypersensitive (allergic) to the active ingredient (isosorbide mononitrate), to other nitrates or to any of the other ingredients this medicine contains (see section 6)
- you suffer from severe anemia (reduction in red blood cells which may cause pale skin, weakness or breathlessness)
- you have had a heart attack (myocardial infarction)
- you have had brain hemorrhage (bleeding)
- you have had a head injury (trauma)
- you have very low blood volume (hypovolemia)
- you have a very low blood pressure
- you are suffering from shock as the blood has stopped circulating properly around your body (circulatory failure)
- you are taking sildenafil, tadalafil or vardenafil (medicines to treat erectile dysfunction and/or pulmonary hypertension) or any other phosphodiesterase inhibitor
- you have an eye disease called glaucoma
- you have been diagnosed with any of the following heart conditions: hypertrophic obstructive cardiomyopathy (HOCM), constrictive pericarditis, cardiac tamponade, low cardiac filling pressures, aortic/mitral valve stenosis, diseases associated with raised intracranial pressure
- you take products that contain riociguat, a medicine used to treat pulmonary hypertension

If any of the above conditions applies to you, consult the doctor or pharmacist.

Special warnings regarding the use of the medicine

Before the treatment with Monocord, tell the doctor if:

- you have a recent history of heart attack, or the left side of your heart is not working properly. It is important that blood pressure does not fall too low
- you have underactive thyroid gland
- you are malnourished (severely underfed)
- you have liver or kidney disease
- you suffer from hypothermia (very low body temperature)
- you suffer from very poor circulation
- you have abnormally low level of oxygen in the blood and impaired gas exchange due to lung disease or ischemic heart failure
- you have a recent history of orthostatic dysfunction (a situation in which a drop in blood pressure and symptoms, such as lightheadedness, fast heart beat or even fainting, occur upon standing up and are relieved by lying down).

Drug interactions

- **Do not take Monocord with phosphodiesterase inhibitors such as sildenafil, tadalafil or vardenafil, used for impotence. Concomitant use of Monocord with these medicines can cause your blood pressure to fall to a dangerously low level. Do not stop the treatment with Monocord in order to take these medicines, as this will increase your chances of having an angina attack.**
- **Do not take Monocord with products that contain riociguat.**

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

Especially if you are taking:

- Medicines which can lower the blood pressure such as: beta blockers (atenolol, propranolol), calcium channel blockers (nifedipine, diltiazem), vasodilators (glycerol trinitrate, methyldopa), angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (olmesartan medoxomil, candesartan cilexetil), monoamine oxidase inhibitors, alprostadil
- Tricyclic antidepressants such as amitriptyline, clomipramine (to treat depression)
- Neuroleptics to treat psychosis (delusions, hallucinations and/or disordered thought) such as phenothiazines (fluphenazine) or butyrophenones (haloperidol)
- Ergotamine, for the treatment of migraine
- Aldesleukin (for the treatment of kidney cancer)
- Medicines that contain sapropterine for the treatment of hyperphenylalaninemia (HPA)

Use of the medicine and alcohol consumption

Do not drink alcohol. It could increase the effect of **Monocord** and lower the blood pressure too much. If this happens, you may feel dizzy or faint.

Decreased gastrointestinal transit time

If you have decreased gastrointestinal transit time (food passes through your stomach and bowels more quickly than it should), **Monocord** could have less effect than expected.

Pregnancy, breastfeeding and fertility

If you are pregnant, trying to become pregnant or breastfeeding, consult the doctor or pharmacist before taking **Monocord**. The doctor will decide if you should take this medicine.

Driving and using machines

Monocord may cause headache, blurred vision, dizziness, or tiredness – these effects are increased in combination with alcohol. If this happens to you, do not drive or use machines.

Important information about some of the ingredients of the medicine

Monocord contains lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking this medicine.

Monocord 20, 40: The medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to use the medicine?

Always use the 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.

This medicine is usually not intended for children and infants.

Do not take Monocord to treat a sudden attack of angina pectoris. Consult the doctor about a different medicine to be taken during a sudden angina attack.

Method of administration

Monocord 20, 40:

- The tablet can be halved. There is no information about crushing/chewing.
- Take the medicine with water.
- Take the medicine on an empty stomach, approximately one hour before or two hours after a meal.

Monocord 50 SR:

- Do not halve, crush or chew the tablet as it is a slow release tablet. Swallow the medicine whole with a glass of water.
- Take the medicine in the morning on an empty stomach, approximately one hour before or two hours after a meal.
- You may find undissolved tablet residues in your stools. Pay attention to this phenomenon, especially if you have frequent bowel movements, diarrhea or digestive problems, and report it to the doctor as you may not received the necessary dosage.

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.

Too much **Monocord** may cause your blood pressure to fall too low, making you feel sick, faint and dizzy. Looking pale, sweating, weak pulse, quick heartbeat, lightheadedness on standing, headache, weakness, dizziness, nausea or vomiting, diarrhea may also occur.

Taking too much **Monocord** may cause purple coloration of the skin and mucous membranes, rapid breathing and shortness of breath (methemoglobinemia). A very large overdose can cause increased pressure in the head, a coma or collapse and require immediate resuscitation.

If you forgot to take the medicine

If you forgot to take this medicine at the designated time, do not take a double dose to make up for a forgotten dose. Skip the forgotten dose and take the next dose at the regular time.

If you stop taking the medicine

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 your condition may get worse.

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 **Monocord** 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.

Seek immediate medical assistance if you have any of the following:

- Difficulty breathing
- Swelling of the eyelids, face or lips
- Rash or itching especially those covering the whole body
- Collapse
- Fainting
- Exfoliative dermatitis (serious illness with widespread redness of the skin, accompanied by scaling, peeling, and flaking of the skin, and may include itching and hair loss)
- Severe decreases in blood pressure with nausea, vomiting, restlessness, looking pale, and excessive sweating, which have been reported during treatment with drugs in the same class as **Monocord**
- Increased chest pain due to a lack of oxygen to the heart muscle and areas around the heart

Contact the doctor immediately if you experience any symptoms of shock or collapse after the first dose.

Very common side effects (effects that occur in more than 1 in 10 users):

- Headache

Common side effects (effects that occur in 1-10 out of 100 users):

- Lightheadedness on standing upright
- Dizziness
- Sleepiness
- Weakness
- Fast heartbeat
- Drowsiness

These effects can occur in the first days of treatment or after increasing the dosage.

Uncommon side effects (effects that occur in 1-10 out of 1,000 users):

- Fainting or collapse, sometimes accompanied by slow, abnormal heart rate
- Nausea or vomiting
- Skin rashes
- **Worsening of angina pectoris** (tight pain in the chest, neck or arm area)
- Flushing

Very rare side effects (effects that occur in less than 1 in 10,000 users):

- Heartburn

Side effects with unknown frequency (effects for which a frequency has not yet been determined):

- Low blood pressure

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 תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Do not store above 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, the medicine also contains:

Monocord 20, 40:

Lactose monohydrate, compressible sugar, sodium starch glycolate, hypromellose, magnesium stearate, titanium dioxide (E171), silica colloidal anhydrous, macrogol 400, carnauba wax.

Monocord 20 also contains: Indigo carmine aluminum lake (E132), erythrosine aluminum lake (E127)

Monocord 40 also contains: Copovidone

Monocord 50 SR:

Hypromellose, compressible sugar, lactose monohydrate, magnesium stearate, titanium dioxide (E171), silica colloidal anhydrous, erythrosine aluminum lake (E127), quinoline yellow aluminum lake (E104), macrogol 400, indigo carmine aluminum lake (E132), carnauba wax.

What the medicine looks like and what the package contains

Monocord 20: purple, biconvex, coated tablet, with a score line on one side.

Approved package sizes: 10, 28, 30, 50, 60 tablets. Not all package sizes may be marketed.

Monocord 40: white, round, coated tablet, with a score line on one side.

Approved package sizes: 10, 28, 30, 50 tablets. Not all package sizes may be marketed.

Monocord 50 SR: red, round, coated tablet.

Approved package sizes: 10, 28, 30, 50 tablets. Not all package sizes may be marketed.

Revised in December 2023 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:

Monocord 20: 052-51-23128-00

Monocord 40: 049-99-26415-00

Monocord 50 SR: 050-88-26416-00

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