

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

Monocord® 20, 40, Tablets

Monocord® 50 SR, Slow release tablets

Monocord 20: Each tablet contains isosorbide mononitrate 20 mg.

Monocord 40: Each tablet contains isosorbide mononitrate 40 mg.

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 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 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 dilating blood vessels in the heart to increase the blood supply to the heart. Angina pectoris usually shows as a pressing 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 receiving 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 (a decrease in red blood cells, which may cause pale skin, weakness or shortness of breath)
- you have had a heart attack (myocardial infarction)
- you have had brain hemorrhage (bleeding)
- you have had a head injury (trauma)
- you have severely low blood volume (hypovolemia)
- you have a very low blood pressure
- you are suffering from shock because the blood has stopped flowing properly in your body (blood flow failure)
- you are taking sildenafil, tadalafil or vardenafil (medicines to treat impotence and/or pulmonary hypertension) or any other phosphodiesterase inhibitor
- you have an eye disease called glaucoma
- you have been diagnosed with one of the following heart problems: hypertrophic obstructive cardiomyopathy (HOCM), constrictive pericarditis, cardiac tamponade, low cardiac filling pressures, aortic/mitral valve stenosis, diseases associated with raised intracranial pressure

- you take medicines that contain ricoguat, a medicine used to treat pulmonary hypertension
- If one or more of these conditions apply 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 hypothyroidism
- you suffer from malnutrition
- you have a liver or kidney disease
- you suffer from hypothermia (very low body temperature)
- you suffer from serious blood flow disorders
- you have an unusually low level of oxygen in the blood and failure in gas exchange due to lung disease or ischemic heart failure

Drug interactions

- **Do not take Monocord with phosphodiesterase inhibitors** such as sildenafil, alprostadil, tadalafil or vardenafil, which are used to treat impotence. **Simultaneous use of monocord with these medicines can cause your blood pressure to drop 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 pectoris attack.**
- **Do not take Monocord with preparations containing ricoguat.**

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 that cause a reduction in blood pressure such as: beta blockers (ethenolol, propranolol), calcium channel blockers (nifedipine, diltiazem), vasodilators (glyceryl trinitrate, methyldopa), angiotensin-converting enzyme inhibitors (ACE), angiotensin receptor blockers (olmesartan, medoximil, candesartan cilexetil), monoamine oxidase inhibitors
- Tricyclic antidepressants such as amitriptyline, clomipramine (for the treatment of depression)
- Neuroleptic medicines for the treatment of psychosis (delusions, hallucinations and/or thinking disorders) such as phenothiazines (fluphenazine) or butyphenones (haloperidol)
- Ergotamine for the treatment of migraine
- Aldesleukin (for the treatment of kidney cancer)
- Medicines that contain sarpoterpine for the treatment of hyperphenylalaninemia (HPA)

Use of this medicine and alcohol consumption
Do not drink alcohol. This may increase the effect of **Monocord** and lower blood pressure too much. If this happens you may feel dizzy or faint.

Pregnancy, breastfeeding and fertility

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

Driving and using machines

Monocord may cause you a head

ache, blurred vision, dizziness, or tiredness. If this happens to you, do not drive or use machines.

Important information about some of the ingredients of this medicine

Monocord contains lactose and sucrose. If you have been told in the past by a doctor that you have an intolerance for certain sugars, consult the doctor before taking this medicine.

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

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.

This medicine is not usually intended for children and infants.

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

Manner of treatment

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 an hour before or two hours after the 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 an hour before or two hours after the meal.
- You may find undissolved tablet residues in your stool. 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 have 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. An overdose of **Monocord** can cause blood pressure that is too low, nausea, fainting and dizziness. A very large overdose can cause 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 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 **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 medical assistance immediately if you experience an allergic reaction. The reaction can include the following symptoms:

- Difficulty breathing
- Swelling of the eyelids, face or lips
- Rash or itching especially those covering the whole body
- Collapse
- Fainting
- Exfoliative dermatitis (a serious disease with blistering of the skin, mouth, eyes and genitals)

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

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

• Headache

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

- Dizziness when standing up
- Dizziness
- Sleepiness
- Weakness
- Fast heartbeat
- Drowsiness

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

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

- Fainting or collapse
- Nausea or vomiting
- Skin rashes
- Paleness
- Excessive sweating
- Restlessness

Worsening of angina pectoris (pressing pain in the chest, neck or arm area)

• Flushing

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

• Heartburn

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

- Redness or peeling of the skin (exfoliative dermatitis)
- Low blood pressure
- Swelling of the skin

You may also suffer from increased chest pain due to a lack of oxygen to the heart muscle and areas around the heart.

Very slow heart rate has been reported with the use of nitrates.

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" www.health.gov.il 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 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, this 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: a purple tablet, biconvex, coated, 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: a white tablet, round, coated, 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: a red tablet, round, coated. Approved package sizes: 10, 28, 30, 50 tablets. Not all package sizes may be marketed.

Revised in March 2021 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

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Manufacturer and registration holder:

Dexcel® Ltd.

1 Dexcel St., Or Akiva 3060000, Israel