PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Monolong 40 mg Sustained-Release Capsules

Each sustained-release capsule contains isosorbide-5-mononitrate 40 mg.
For inactive ingredients and allergens in the preparation - see section 2 "Important information about some of the ingredients of the medicine" and section 6.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the 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.

1. What is the medicine intended for?

Treatment of angina pectoris and prevention of angina pectoris attacks.

Therapeutic class: organic nitrates.

Organic nitrates work by dilating blood vessels in the heart in order to increase blood supply to the heart.
Angina pectoris usually manifests as a tight pain in the chest, neck or the arm area. The pain comes from the heart muscle and indicates that a part of it is not receiving enough oxygen as required for its functioning.

2. Before using the medicine:

☒ Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (isosorbide mononitrate), to other nitrates or to any of the additional components the medicine contains (see section 6)
- You have severe anemia (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 bleeding in the brain
- You have had a head injury (trauma)
- You have a severely low blood volume (hypovolemia)
- You have very low blood pressure
- You are in shock as blood has stopped flowing properly in your body (circulatory failure)
- You are taking sildenafil, tadalafil or vardenafil (medicines for treatment of 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, stenosis of the aortic/bicuspid valve, diseases associated with increased intracranial pressure
- You are taking preparations containing riociguat, a medicine used for treatment of pulmonary hypertension

If one or more of the abovementioned conditions apply to you, consult the doctor or pharmacist.

Special warnings regarding the use of the medicine

❗ Before treatment with Monolong, inform the doctor if:

- You have an underactive thyroid
- You are malnourished
- You have liver or kidney disease
- You have hypothermia (very low body temperature)
- You have serious circulatory disturbances
- You have an exceptionally low level of oxygen in the blood and impaired gas exchange due to lung disease or ischemic heart failure

❗ Drug interactions

- **Do not take Monolong together with phosphodiesterase inhibitors, such as: sildenafil, alprostadil, tadalafil or vardenafil, which are used to treat impotence. Concurrent use of Monolong with these medicines may cause your blood pressure to drop dangerously. Do not stop treatment with Monolong in order to take these medicines, as this will increase your risk for an angina pectoris attack.**
- **Do not take Monolong together with preparations containing riociguat.**

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

- Medicines that lower blood pressure, such as: beta blockers (atenolol, propranolol), calcium channel blockers (nifedipine, diltiazem), vasodilators (glyceryl trinitrate, methyldopa), angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (olmesartan, medoxomil, candesartan cilexetil), monoamine oxidase inhibitors
- Tricyclic antidepressants, such as: amitriptyline, clomipramine (for treatment of depression)
- Neuroleptic medicines for treatment of psychosis (delusions, hallucinations and/or thinking disorder), such as: phenothiazines (fluphenazine) or butyrophenones (haloperidol)
- Ergotamine for treatment of migraines
- Aldesleukin (for treatment of renal cancer)
- Medicines containing sapropterin for treatment of hyperphenylalaninemia (HPA)

❗ Use of the medicine and alcohol consumption
Do not drink alcohol. Alcohol may augment the effect of Monolong and decrease the 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 with the doctor or pharmacist before taking Monolong. The doctor will decide if you should take this medicine.

❗ Driving and operating machinery
Monolong may cause headache, blurred vision, dizziness or tiredness. If this happens to you, do not drive or operate machinery.

❗ Important information about some of the ingredients of the medicine
Monolong contains lactose and sucrose. If you have been told by a doctor that you have an intolerance to some sugars, consult your doctor before taking this medicine.
Monolong contains an Azo dye, which may cause allergic reactions.

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.
The dosage and treatment regimen will be determined by the doctor only.

Do not exceed the recommended dose.
This medicine is not usually intended for administration to children and infants.

Do not take Monolong for treatment of a sudden attack of angina pectoris. Consult with the doctor regarding another preparation to be taken during a sudden attack of angina pectoris.

Method of administration

- Do not open and scatter the content of the capsule, as this is a sustained-release capsule. The capsule should be swallowed whole with a glass of water
- The medicine should be taken in the morning on an empty stomach, about one hour before or two hours after a meal

If you accidentally took a higher dosage
If you took an overdose or if a child swallowed this medicine by mistake, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you. An overdose of Monolong may cause blood pressure to be too low, nausea, fainting and dizziness.
A very large overdose may 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 required time, do not take a double dose to compensate for a forgotten dose. Skip the forgotten dose and take the next dose at the usual time.

If you stop taking the medicine
Follow the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the 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 every time you take a medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Monolong may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

If you are experiencing an allergic reaction, seek medical aid immediately. The reaction may include the following symptoms:

- Breathing difficulties
- Swelling of the eyelids, face or lips
- Rash or itching, especially those covering the entire body
- Collapsing
- Fainting
- Exfoliative dermatitis (a serious disease with blisters on the skin and in the mouth, eyes and genitals)

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

Very common side effects (side effects that occur in more than one out of ten users):

- Headache

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

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

These effects may appear in the first days of treatment or following a dose increase.

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

- Fainting or collapsing
- Nausea or vomiting
- Skin rashes
- Pallor
- Increased sweating
- Restlessness
- **Worsening of angina pectoris** (tight pain in the chest, neck or the arm area)
- Flushing

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

- Heartburn

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

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

You may also suffer from increased chest pain due to insufficient oxygen supply to the heart muscle and to areas around the heart.
Very slow heartbeat has been reported with nitrate use.

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

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il/

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
Do not use the medicine after the expiry date (Exp.) appearing on the package. The expiry date refers to the last day of that month.
Storage: Store at temperature below 25°C.

6. Additional information:

In addition to the active ingredient, the medicine also contains:
Lactose, Sucrose, Gelatine, Shellac, Maize starch, Purified Talc, Eudragit L-100, Eudragit RS-100, Titanium Dioxide, Azorubine, Indigo Carmine.
What does the medicine look like and what are the contents of the package:
Each Monolong capsule contains yellowish granules and is made of a clear and colorless body and an opaque purplish cap.
Approved package sizes: 20, 30, 100 capsules.
Not all package sizes may be marketed.
Name and address of the Manufacturer and Marketing Authorization Holder: CTS Chemical Industries Ltd., 3 Hakidma st., Kiryat Malachi.
This leaflet was revised in October 2021 in accordance with the Ministry of Health guidelines.
Registration number of the medicine in the national drug registry of the Ministry of Health: 052-97-26218-00

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