

PACKAGE LEAFLET: Information for the patient

MONOPAN

Tablets – 40 mg

(Isosorbide 5-mononitrate)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects worsens or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Monopan is and what it is used for
2. Before you take Monopan
3. How to take Monopan
4. Possible side effects
5. How to store Monopan
6. Further information

1. WHAT MONOPAN IS AND WHAT IT IS USED FOR

Monopan contains as active substance isosorbide 5 – mononitrate, which belongs to the group of nitrates with a vasodilator action. Nitrates are used for the treatment and prevention of the symptoms of angina pectoris (chest pain) and other heart conditions including heart failure.

Angina is a pain or tightness of the chest caused by lack of oxygen reaching the heart muscle.

Nitrates work in two different ways. They widen the arteries that carry blood to the heart muscle and relax the veins that return blood from the body to the heart. Both these actions allow more oxygen to reach the heart muscle and reduce the work of the heart. In this way an acute attack of angina is prevented and the pain associated with an acute attack of angina is relieved.

2. BEFORE YOU TAKE MONOPAN

Do not take Monopan:

- in cases of hypersensitivity to the active substance, to nitrates or any of the excipients of the tablet;
- in acute circulatory failure, associated with marked hypotension (shock, states of collapse);
- in hypovolemia;
- if you have severe anemia;
- in conditions associated with elevated intracranial pressure;
- if you suffer from these heart problems (aortic or mitral stenosis, constrictive pericarditis, cardiac tamponade, hypertrophic cardiomyopathy);
- simultaneously with sildenafil citrate (Viagra) because sildenafil may amplify the vasodilatory effects of isosorbide resulting in severe hypotension;
- if you have toxic pulmonary oedema;
- if you take products that contain riociguat, a medicine used in treating pulmonary hypertension.

Take special care with Monopan

Ask your doctor before taking Monopan and make sure your doctor knows that you:

- are pregnant, or breastfeeding;
- are allergic to this medicine or any other similar medicine (of the class of nitrates);
- suffer from heart problems, or you have liver or kidney problems;
- suffer from hypotension;
- have recently suffered a head trauma or cerebral haemorrhage;
- suffer from anaemia, malnutrition;
- suffer from thyroids;
- suffer from glaucoma;
- are taking other medicines to treat erectile dysfunction;
- have hypothermia, lack of oxygen in the blood and abnormal ventilation;
- have developed drug tolerance.

Taking other medicines

Concomitant treatment with other medicines may affect or be affected by Monopan. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription. Do not forget to inform your doctor about the treatment with isosorbide mononitrate if you are prescribed another medicine during the treatment.

Concomitant treatment with other vasodilators, calcium-channel blockers, ACE-inhibitors, beta-blockers, antihypertensives, tricyclic antidepressants, major tranquilizers, may potentiate the hypotensive effect of Monopan.

Concomitant administration with dihydroergotamine may increase the bioavailability of dihydroergotamine. Special attention should be paid at this point to patients with artery-coronary diseases, because dihydroergotamine antagonises the effects of nitrates and may lead to coronary vasoconstriction.

The possibility that acetylsalicylic acid and other non - steroidal antiinflammatory drugs might diminish the therapeutic response of Monopan, cannot be excluded.

Do not take Monopan with phosphodiesterase inhibitors such as sildenafil (“Viagra”) used for impotence. Using Monopan with these medicines could cause dangerous hypotension. You must not stop taking Monopan to take sildenafil as this will increase your chances of having an angina attack.

Do not take Monopan with products that contain riociguat (a medicine used in treating pulmonary hypertension) or sapropterine (used for phenylketonuria).

Taking Monopan with food and drinks

The consumption of alcohol may potentiate the hypotensive effect of this medicine.

Pregnancy

Ask your doctor or pharmacist for advice before taking this medicine.

As a general rule, no drugs should be taken during the first trimester of pregnancy.

The benefits and risks of taking drugs should be carefully considered throughout the whole pregnancy.

The use of this medicine must be limited, although no adverse effects in the fetus have been reported. The medicine should be used during pregnancy only if its use is essential.

Breastfeeding

It is not known whether the medicine passes into breast milk. The benefits for the mother must be weighed against the risks for the baby.

Driving and using machines

Even when taken as directed by the doctor, it can impair the patient's ability to drive and operate machinery. This effect may happen especially at the beginning of the treatment, when the medicine is changed, or if alcohol is consumed.

Important information about some of the excipients of Monopan

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

3. HOW TO TAKE MONOPAN

Always take this medicine exactly as your doctor has told you. You should tell your doctor or pharmacist if you are not sure. If you feel that the effects of Monopan are too strong or too weak, talk to your doctor or pharmacist. The tablets should be swallowed with at least half glass of water.

General rules

Monopan is not intended to be used for the treatment of acute attacks of angina pectoris; if they occur during treatment, the additional use of rapid - acting nitrate preparations is indicated.

An abrupt cessation of the treatment is not recommended because there is a risk of an attack.

Tablets are divisible, which allows dosage adjustment as required.

Development of tolerance may occur in individual patients with long-acting nitrates (such as isosorbide) during long-term treatment.

Angina pectoris

Treatment begins with ½ tablet twice daily and the dosage may be increased by adding ½ of a 40 mg tablet according to patient conditions.

Maximal dosage can reach up to 80 mg daily.

Chronic heart failure

In cases of chronic heart failure treatment, it should start in the hospital, where the patient's hemodynamic status is monitored and the treatment should also be continued in hospital until the requisite maintenance dosage has been established.

Children

No information is available on the use of the medicine in children.

If you take more Monopan than you should

The patient must be under medical attention. Symptoms of Monopan overdose include: severe headache, difficulty in breathing and swallowing, muscle cramps, vomiting, nausea, diarrhea, chills, pallor, irregular heartbeats, irregular vision and seizures.

If you forget to take Monopan

If you forget a dose, take the following dose as soon as you can. If your next dose is after 2 hours, skip the dose you missed and take only your next regularly scheduled dose.

Do not take a double dose of this medication.

If you stop taking Monopan

If you are not sure how to use this medicine, consult your doctor or pharmacist. This medicine should not be discontinued immediately, but gradually because immediate discontinuation may cause angina attacks.

If you have any further question on the use of this medicinal product, ask your doctor or your pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Monopan can cause side effects, although not everybody manifests them.

The frequency of possible side effects is shown in the table below:

Very common:	occur in more than 1 in 10 users
Common:	occur in less than 1 in 10, but more than 1 in 100 users
Uncommon:	occur in less than 1 in 100, but more than 1 in 1,000 users
Rare:	occur in less than 1 in 1,000, but more than 1 in 10,000 users
Very rare:	occur in less than 1 in 10,000 users
Frequency not known	the frequency cannot be determined from the available data

Very common

In the Central Nervous System

Like all other nitrate preparations, Monopan may give rise to headache, which is due to cerebral vasodilatation and is dose-dependent. Headache regresses after a few days of therapy. If it does not disappear, it can be treated with analgesics. In cases where treatment with analgesics is ineffective, the dosage of Monopan should be reduced or use of the product discontinued.

Common

In the cardiovascular system

Facial flushing, faintness, postural hypotension which can induce reflex tachycardia. This can be avoided by the combination with a beta - blocker.

In the Central Nervous System: dizziness, drowsiness, cerebral ischaemia.

In the gastrointestinal tract: nausea, vomiting.

Uncommon

In the cardiovascular system: circulatory collapse, syncope.

In the gastrointestinal tract: diarrhoea.

In the skin: skin reactions.

Rare or very rare

Myalgia.

5. HOW TO STORE MONOPAN

Keep out of the reach and sight of children.

Do not use after the expiry date which is stated on the package.

Do not store above 25°C.

Store in the original package in order to protect it from light.

6. FURTHER INFORMATION

What Monopan contains

The **active substance** is isosorbide 5-mononitrate.

Each tablet contains 40 mg of isosorbide 5-mononitrate.

The **excipients** are: microcrystalline cellulose, lactose monohydrate, maize starch, pregelatinised starch, magnesium stearate, colloidal silicon dioxide, red iron oxide (E 172).

Contents of the pack

Carton box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in September 2023.