PACKAGE LEAFLET: INFORMATION FOR THE USER

DILCORAN 80

80 mg, modified-release tablets

PENTAERYTHRITYL TETRA NITRATE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• 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 only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. WHAT DILCORAN 80 IS AND WHAT IT IS USED FOR

DILCORAN 80 is a medicine used to treat circulatory disorders of the coronary arteries. DILCORAN 80 is used for prevention and long-term treatment of pain in the chest due to a disorder of circulation in coronary arteries (angina pectoris).

Warning:
DILCORAN 80 is not suitable for the treatment of acute attacks of angina pectoris.

2. BEFORE YOU TAKE DILCORAN 80

Do not use DILCORAN 80:

• If you are hypersensitive to the active substance pentaerythrityl tetra nitrate and other nitric compounds or to any other substances of the medicinal product DILCORAN 80.
• in case of acute circulatory weakness (shock, circulatory collapse).
• in a state of shock caused by cardiac weakness (cardiogenic shock), unless appropriate measures are secured, sufficiently high pressure of filling the heart (left ventricle pressure at the end of diastole).

- in acute myocardial infarction.
- if you have very low blood pressure (strongly expressed hypotension), for example, systolic blood pressure below 90 mmHg.

During therapy with DILCORAN 80 do not use products for the treatment of erectile dysfunction that contain Phosphodiesterase 5 inhibitors as active substance such as sildenafil, vardenafil or tadalafil, because this may cause hypertensive effect.

DILCORAN 80 should be disregarded even when using products for the treatment of erectile dysfunction, which contain Phosphodiesterase 5 inhibitors as the active substance such as sildenafil, vardenafil or tadalafil, or during an acute attack of angina pectoris.

Take special care when taking Dilcoran 80:

- If you have a heart muscle disorder that is characterized by a narrowing of the inside of the heart (hypertrophic obstructive cardiomyopathy), constrictive pericarditis or pericardial tamponade (pericardial tamponade).
- In low-pressure of filling the heart, for example during acute myocardial infarction, reduced function of the left ventricle (left ventricle weakness) you should avoid lowering of systolic blood pressure below 90 mmHg.
- If you have heart valve damage of left ventricle and narrowing (aortic and / or mitral stenosis).
- If you have problems controling "lower" blood pressure (orthostatic hypotension).
- In diseases that are associated with an increase in intracranial pressure (so far the further increase in blood pressure was observed only during the application of high-dose intravenous nitroglycerin).

Dilcoran 80 is not suitable for the treatment of acute attacks of angina pectoris.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those that can be obtained without a prescription.

Hypotensive effect is intensified by:

- Other vasodilators.
- Medicines for lowering blood pressure (e.g., beta-blockers, diuretics, calcium channel blockers, ACE inhibitors).
- medicines for treatment of mental disorders, such as depression and neuroleptics.
- Alcohol.
- Products that are used to treat erectile dysfunction, which contain Phosphodiesterase 5 inhibitors such as sildenafil, vardenafil, and tadalafil.

Concomitant use of DILCORAN 80 with dihydroergotamine can lead to increased levels of Dihydroergotamine and its effects on blood pressure.

Taking dilcoran 80 with food or drinks

DILCORAN 80 tablets should be swallowed with water. Tablets can be taken with or without meals.
Do not take alcohol during the administration of DILCORAN 80.

Pregnancy and breastfeeding

Before you start that you are taking any medicine, consult your doctor or pharmacist.
If you are pregnant, Dicloran 80 should only be used based on the opinions and instructions of your doctor, because there is not enough experience with the use of this medicine in pregnant women.
If you are breastfeeding, Dilcoran 80 should only be used based on the opinions and instructions of your doctor, it is not known if Dilcoran 80 is excreted into the breast milk. When applying Dilcoran 80 during breast-feeding, you should be aware of possible side effects that could be caused in the infant.

Driving and using machines

This medicine can, even at the recommended doses, have effect on reactions, ability of active use of a motor vehicle or use of machinery, or work in potentially dangerous circumstances. This refers to the beginning of administration of the medicine, increasing the dose of the medicine or change of the medicine, and the concomitant use of alcohol and medicine.

3. HOW TO TAKE DILCORAN 80

Always take DILCORAN 80 according to the recommendations of your doctor. If you are not sure, check with your doctor or pharmacist.
Dosage is determined by the physician on individual basis and it epends on the seriousness of the disease. The recommended daily dose in severe cases is by one tablet in the morning and in the evening (equivalent to 160mg of pentaerythrityl tetra nitrate). For continued treatment and in other cases, ½ of tablet is taken in the morning and in the evening (equivalent to 80 mg pentaerythrityl tetra nitrate).

Method of administration

Swallow the tablet with enough liquid (e.g., a glass of water).

Duration of treatment

Duration of treatment and mode of administration will be determined by your doctor.
If you have the impression that DILCORAN 80 has too strong or too weak effect on you, talk about it with your doctor.

If you take more medicine than you should

If you take more tablets than what is recommended (overdose) immediately seek medical attention. If possible take your tablets or box to show to your doctor.
Depending on the degree of overdose, hypotension can cause reflexive acceleration of pulse, weakness, dizziness and fainting, headache, facial flushing, nausea, vomiting and diarrhea.
During overdose with high doses of Dilcoran 80 (approximately 20 mg / kg body weight), as a result of decomposition pentaeritiethyl tetranitrate to ion nitrate, methemoglobinemia (conversion of hemoglobin into a form that cannot carry oxygen), cyanosis (bluish color of the skin caused by lack of oxygen) and acceleration of breathing occur.

If you forget to take Dilcoran 80

Never take a double dose to replace the missed dose of the medicine.

If you suddenly stop taking Dilcoran 80

Do not stop the treatment without consulting your doctor, because otherwise the effect of treatment can be compromised.
If you have any additional questions about the use of the medicines, talk to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Medicine DILCORAN 80, as well as other medicines, can cause side effects, although not everybody gets them.
Side effects are listed according to the following categories of frequency:

Very common: occurs in more than 1 in 10 patients who take the medicine
Common: occurs in 1 to 10 in 100 patients
Uncommon: occurs in 1 to 10 in 1000 patients
Rare: occurs in 1 to 10 to 10000 patients
Very rare: occurs in less than 1 in 10000 patients
Unknown frequency: cannot be estimated on the basis of the available data

Especially at the beginning of treatment you may experience intermittent pressure and headache (i.e. nitric headache), which disappears after a few days, but it may reappear.

Cardiovascular disorders

Common*:* at the beginning of the treatment, but also when changing the dose, fall in blood pressure and/or postural control disorders of circulation (orthostatic hypotension), with increasing speed of the pulse, faintness, nausea and weakness may occur.

Uncommon*:* Pronounced hypotension with tightening in the heart area (the symptoms of angina pectoris), often with arrhythmias with slower heart rate (bradycardic arrhythmias) and sudden loss of consciousness (syncope).

Gastrointestinal tract

Uncommon: nausea, vomiting.

Disorders of skin and subcutaneous tissue:

Uncommon: Transient Erythema (redness) and cutaneous allergic reactions.

Very rare*:* severe inflammatory disease of the skin (exfoliative dermatitis/Stevens Johnson's syndrome or angioedema).

Note

The use of Dilcoran 80 may cause relative redistribution of blood flow in less ventilated parts of lungs and the temporary reduction of oxygen content in arterial blood, which in patients with circulatory disorders in the coronary arteries (coronary artery disease) can cause a decrease in oxygen supply of the heart muscle.

When used at the recommended dose range, Dilcoran 80 does not cause the effect of weakening. However, the attention is drawn to the well-known possibility of developing tolerance or cross-tolerance to other nitro compounds that occurs in other medicines from this group..

With the first signs of side effects, medicine Dilcoran 80 should not be used any further. If you notice some of these side effects, tell your doctor so that he/she could decide on the severity and necessary actions.

Reporting of side effects

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE DILCORAN 80

Keep out of reach of children!

Shelf life:3 years.

Do not use dilcoran 80 after the expiration date stated on the package. Shelf life expires on the last day of that month.

Store below 25 ° c. Store in the original packaging to protect it from light and moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What contains Dilcoran 80

Each tablet contains 80 mg of pentaerythrityl tetranitrate.

The other ingredients are:

Stearic acid; Lactose monohydrate; Sodium carboxymethyl cellulose 300; Castor oil, hydrogenated; MACROGOL 4000; Magnesium stearate; Silicon dioxide, colloidal anhydrous; FDC Yellow No. 6 C.I. 15985.

How does Dilcoran 80 looks like and contents of the pack

Ellipsoidal, bi-convex, double layered, light orange and orange-colored tablets with the division line in the form of a groove on both sides.
Blister PVC/aluminum foil. Each blister contains 10 tablets.
The basic box contains 2 blisters. The basic box also contains patient information leaflet.

Regime of dispensing

The medicine is issued on doctor's prescription.

Manufacturer

Hemofarm proizvodnja farmaceutskih proizvoda d.o.o. Banja Luka
Novakovići bb, Banjaluka, Bosnia and Herzegovina

Manufacturer of the medicinal product

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