

PACKAGE LEAFLET: INFORMATION FOR THE USER

DOXILEK

500 mg capsule, hard

CALCIUM DOBESILATE

• 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 DOXILEK tablets is and what it is used for
2. Before you take DOXILEK
3. How to take use DOXILEK
4. Possible side effects
5. How to store DOXILEK
6. Further information

1. WHAT DOXILEK IS AND WHAT IT IS USED FOR

Calcium dobesilate acts selectively on the capillary walls regulating their physiological functions of resistance and permeability.

DOXILEK is prescribed for

- the prevention and treatment of damage to the blood vessels of the eye, which may occur in patients with diabetes mellitus (diabetic retinopathy)
- the prevention and treatment of damage to the capillaries in the case of pathological alteration in the venous circulation of the lower extremities, associated with edema.

2. BEFORE YOU TAKE DOXILEK

Do not take DOXILEK

- if you are allergic (hypersensitive) to Calcium dobesilate, or to any of the other ingredients in this medicine

Take special care with DOXILEK, so you must tell the doctor if you

- are pregnant, trying to get pregnant or breast-feeding
- have recurrent gastritis (recurrent (repeated) inflammation of the gastric mucosa) and peptic ulcer disease (a disease caused by bacterial infection, and sometimes long-term application of non-steroidal anti-inflammatory drugs (NSAIDs))
- have impaired liver or kidney function

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

There have not been reported significant interactions with other medicines when taking DOXILEK.

Taking DOXILEK with food and drink

Food has no impact on the effect of DOXILEK.

Take the capsules with a meal.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before using any medicine.

Tell your doctor if you are pregnant, think you might be pregnant or planning to become pregnant. DOXILEK is not recommended during pregnancy and breastfeeding.

Driving and using machines

DOXILEK should not affect your ability to drive and use machines.

Important information

DOXILEK tablets contain lactose. So if you suffer from some form of sugar intolerance, tell your doctor before taking this medication. These capsules also contain two colors, azorubine E122 and black PN E151 which may cause allergic reactions (possibly delayed reaction).

3. HOW TO TAKE DOXILEK

Always take DOXILEK exactly as you are told by your doctor. If you are unsure, check with your doctor or pharmacist.

The daily dose and duration of treatment will depend on your disease. So your doctor will tell you how often you should take the capsule and for how long.

The capsules should be taken with a meal. Swallow them whole, unopened, with a little water.

If you take more DOXILEK than you should

If you have taken a higher dose of DOXILEK than the doctor recommended, you should consult your doctor or pharmacist, although there are no reported clinically significant cases of overdose.

If you forget to take DOXILEK

If you miss a dose, take the next dose at the usual time and continue to take the medicine as instructed by a doctor.

Do not take a double dose to make up for a forgotten dose.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, DOXILEK can cause side effects, although not everybody gets them.

The following side effects have been reported:

- Common (may occur in more than 1 in 100 and less than 1 in 10 patients): nausea, abdominal pain, vomiting, fever, joint pain
- Rare (may occur in less than 1 in 1,000 patients): agranulocytosis (very low number of white blood cell), rash.

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 DOXILEK

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use DOXILEK after the expiry date which is stated on the label, 5 years from the date of manufacture.

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 DOXILEK contains

The active ingredient is calcium dobesilate.

The other ingredients are:

Capsule content: lactose monohydrate, povidone, magnesium stearate, sodium lauryl sulphate

Capsule shell: Gelatin

The colors: titanium dioxide E171, blue V E131, black PN E151, yellow iron oxide E172, quinoline yellow E104, azorubine E122

What DOXILEK looks like and contents of the pack

Doxilek hard capsules contain 500 mg of calcium dobesilate.

Boxes with 3 blister packs of 10 hard capsules.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

LEK FARMACEVTSKA DRUŽBA D.D.

VEROVŠKOVA 57, LJUBLJANA, REPUBLIKA SLOVENIJA

Manufacturer of the medicinal product

LEK FARMACEVTSKA DRUŽBA D.D.

VEROVŠKOVA 57, LJUBLJANA, REPUBLIKA SLOVENIJA