

DOBESIL
(Calcium Dobesilate Monohydrate Capsules 500 mg)
Module 1



1.6.3 PATIENT INFORMATION LEAFLET (PIL)

DOBESIL (Calcium Dobesilate Monohydrate Capsules 500 mg)

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 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 is DOBESIL and what it is used for?
2. What you need to know before you use DOBESIL
3. How to use DOBESIL
4. Possible side effects
5. How to store DOBESIL
6. Contents of the pack and other information

1. WHAT IS DOBESIL AND WHAT IT IS USED FOR

DOBESIL is indicated for the treatment of Heaviness in legs, leg cramps, Ankle edema, Varicose Veins, Diabetic foot ulcers, Hemorrhoids, Varicose Veins, Chronic Venous Insufficiency and Diabetic Retinopathy.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE DOBESIL

Hypersensitivity to calcium dobesilate.

3. HOW TO USE DOBESIL

Always use this medicine exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

1 capsule twice in a day for 3 weeks and followed by 1 capsule once a day at least for a month. After meals. Dosage should be individualized depending on severity of the case.

Mode of Administration: For oral use only.

4. POSSIBLE SIDE EFFECTS

Drug induced fever, epigastric pain, gastric irritation, pruritus, skin rashes and granulocytosis (rare).

5. HOW TO STORE DOBESIL

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Keep this medicine out of the sight and reach of children.

Store below 30⁰ C. Protect from light & moisture.

Keep the tube tightly closed.

Do not use this medicine after the expiry date which is stated on the carton and tube after “EXP”.

The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

6. FURTHER INFORMATION

What DOBESIL contains

- The active substances are Calcium Dobesilate Monohydrate BP. Each capsule contains 500 mg Calcium Dobesilate Monohydrate BP.
- The other ingredients are Magnesium Stearate BP & Colloidal Anhydrous Silica BP has been added.

7. What DOBESIL looks like and contents of the pack

This medicinal product is A Yellow coloured body and Green coloured cap size ‘1’ unprinted hard gelatin capsule shell containing white powder.

10 Capsules in Alu /PVDC Blister & 5 such Blister in a carton = 5 x 10’s = 50 Capsules.

8. Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Ochoa Laboratories

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Manufacturer

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8 Date of Revision of PIL