1.6 Product Information

1.6.1 PRESCRIBING INFORMATION (SUMMARY OF PRODUCTS CHARACTERISTICS)

(SPC, CONTAINER LABELING & PATIENT INFORMATION LEAFLET, MOCK-UPS AND SPECIMENS)

SPC – Summary of the Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

DOBESIL (Calcium Dobesilate Monohydrate Capsules 500 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:
Calcium Dobesilate Monohydrate BP 500 mg
Excipients Q.S

For full list of Excipients refer 6.1.

3. PHARMACEUTICAL FORM

A Yellow coloured body and Green coloured cap size '1' unprinted hard gelatin capsule shell containing white powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
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.

4.2 Posology and method of administration
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.

Method of Administration: For oral use only.

4.3 Contraindications
Hypersensitivity to calcium dobesilate.

4.4 Special warnings and special precautions for use

Special Precautions
Duodenal or peptic ulcer, recurrent gastritis. In case of severe renal insufficiency requiring dialysis, the dose should be reduced.

4.5 Interaction with other medicinal products and other forms of Interaction
Not Available

4.6 Pregnancy and lactation
Calcium dobesilate shows no teratogenic effects as it does not cross the placental barrier. Hence, it may be used during; however the experience with same in clinical practice is limited in pregnancy.
Exercise caution since safety for use in the nursing mothers has not been established.

4.7 Effects on ability to drive and use machines
DOBESIL has no or negligible influence on the ability to drive and use machines.

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

4.9 Overdose
Treatment is supportive and symptomatic. Perform induced emesis and gastric lavage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
ATC-code: C05BX01
It increases endothelial nitric oxide levels by enhancing the activity of nitric-oxide synthase, decreasing capillary hyper-permeability. Calcium dobesilate shows anti-platelet and fibrinolytic activities by inhibiting platelet activation factor (PAF) and enhancing the release of tissue plasminogen activator (tPA), thereby improving the local blood flow to tissues, otherwise inhibited due to thrombosis. Calcium dobesilate also inhibits the two pathophysiological reactions in diabetes viz polyol pathway and glycation of proteins due to its inhibitory effects on aldose reductase.
Calcium dobesilate acts on the endothelial layer and basement membrane of the capillaries. It reduces histamine and bradykinin - induced hyper permeability. It increases red blood cell membrane flexibility and reduces capillary fragility. Calcium dobesilate can reduce the platelet aggregation stimulated by collagen and thrombin.
Calcium dobesilate may also inhibit the formation of sorbitol, thus providing another possible mechanism for its usefulness in diabetic retinopathy.
Calcium dobesilate has angioprotective action by reduce micravascular permeabilization. Its antiplatelet effect should counteract thrombosis and its reduction of plasma viscosity should prevent stasis.

5.2 Pharmacokinetic properties

It is mainly absorbed from the gastrointestinal tract. It is metabolized and excreted by the kidneys via urine and feces.

5.3 Preclinical safety data

Not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sr. No.	Raw materials	Pharmacopoeia
1	Magnesium Stearate	BP
2	Colloidal Anhydrous Silica	BP

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30^0 C. Protect from light & moisture.

6.5 Nature and contents of container

10 Capsules in Alu /PVDC Blister & 5 such Blister in a carton = 5 x 10's = 50 Capsules.
The shipper will be over printed / labeled the following matter:

6.6 Special precautions for disposal

No special requirements

7. MARKETING AUTHORISATION HOLDER

Ochoa Laboratories
430, Mzz. F, Gundecha Indl. Complex
Akurli Road, kandivali (E).
Mumbai – 400101. India.
E-mail: support@aurochemgroup.com

8. MARKETING AUTHORISATION NUMBER(S)

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9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT