

SUMMARY OF THE PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

CALCIDOP CAPSULES

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

Oral Capsule

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

CALCIDOP 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

CALCIDOP 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

No Excipient has been added.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30⁰ C. Protect from light & moisture.

6.5 Nature and contents of container

10 Capsules in Alu /PVDC Blister & 3 such Blister in a carton = 3 x 10's = 30 Capsules. The shipper will be over printed / labeled the following matter:

6.6 Special precautions for disposal

No special requirements

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

Marketing Authorisation Holder:

Unisel Pharma (K) Ltd.

P. O. Box 39356 code 00623

Nairobi

Manufacturer:

Aurochem Pharmaceuticals (I) Private Limited

8.MARKETING AUTHORISATION NUMBER(S)

H2022/CTD8477/18684

9.DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

14/07/2022

10. DATE OF REVISION OF THE TEXT

14/07/2022