

SUMMARY OF PRODUCT CHARACTERISTICS

DAFLON 500 mg

Film-coated tablets

Micronized purified flavonoid fraction

1. DENOMINATION

DAFLON 500 mg, film-coated tablet.

2. COMPOSITION

	<i>p. tablet</i>
Micronized purified flavonoid fraction.....	500 mg
. Diosmin (90 %).....	450 mg
. Flavonoids expressed as hesperidin (10 %).....	50 mg

Excipients q.s. for one film-coated tablet.

3. PHARMACEUTICAL FORM

Film-coated tablet.

4. CLINICAL DATA

4.1. INDICATIONS

- Treatment of symptoms related to venolymphatic insufficiency (heavy legs, pain, early morning restless legs),
- Treatment of functional symptoms related to acute hemorrhoidal attack.

4.2. DOSAGE AND METHOD OF ADMINISTRATION

- Usual dosage : 2 tablets daily in two divided doses, midday and evening at meal times.
- Acute hemorrhoidal attack : 6 tablets per day for the first 4 days, then 4 tablets per day for 3 days.

4.3. CONTRA-INDICATIONS

Not applicable

4.4. SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Acute hemorrhoidal attack :

Administration of this medicine is no substitute for the specific treatment of other anal disorders. The treatment must be short-term. If the symptoms do not disappear rapidly, proctological examination should be performed and the treatment reviewed.

4.5. DRUG INTERACTIONS AND OTHER FORMS OF INTERACTION

Not applicable

4.6. PREGNANCY AND LACTATION

Pregnancy :

Experimental studies in animals have not demonstrated any teratogenic effect in animals. Furthermore, no adverse effects have been reported to date in humans.

Lactation :

In the absence of data concerning excretion into breast milk, breast feeding is not recommended during treatment.

4.7. EFFECTS ON THE ABILITY TO DRIVE AND USE MACHINES

Not applicable

4.8. SIDE-EFFECTS

A few cases of minor gastrointestinal and neurovegetative disorders have been reported which did not require suspension of treatment.

4.9. OVERDOSAGE

Not applicable

5. PHARMACODYNAMIC PROPERTIES

5.1. PHARMACODYNAMIC PROPERTIES

Venotonic and vascular protector.

- Pharmacology

It is active upon the return vascular system in the following way :

- . it reduces venous distensibility and stasis,
- . in the microcirculation, it normalises capillary permeability and increases capillary resistance.

- Clinical pharmacology

Double blind controlled studies using methods by which the effects of the product on venous haemodynamics could be demonstrated and quantified have confirmed the above pharmacological properties in man.

- . Dose-effect relationship : a statistically significant dose-effect relationship was established with respect to venous plethysmographic parameters : capacitance, distensibility and rate of emptying. The optimum dose-effect ratio was obtained with 2 tablets.

- . Venous tonic activity : DAFLON 500 mg increases venous tone : venous occlusion plethysmography with a mercury stress gauge demonstrated a decrease in the rate of emptying.
- . Microcirculatory activity : double-blind controlled studies showed a statistically significant difference between placebo and the drug. In patients presenting with signs of capillary fragility, DAFLON 500 mg increases capillary resistance, as measured by angiostrometry.

- **Clinical trials**

Double-blind placebo-controlled trials have demonstrated the activity of the drug in phlebology, in the treatment of chronic venous insufficiency of the lower limbs (both functional and organic).

5.2. PHARMACOKINETICS PROPERTIES

In man, following oral administration of the substance containing ¹⁴C Diosmin :

- excretion is mainly faecal, a mean of 14% of the dose administered is excreted in the urine
- the elimination half-life is 11 hours.
- the drug is extensively metabolised as evidenced by the presence of various phenol acids in the urine.

5.3.PRECLINICAL SAFETY DATA

Not applicable.