SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

DAFLON 1000 mg, film coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Micronized, purified flavonoid fraction ..... 1000 mg

Corresponding to:

Diosmin: 90 percent ..... 900 mg

Flavonoids expressed as hesperidin: 10 percent ..... 100 mg

Mean humidity ..... 40 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film coated tablet.

4. CLINICAL DATA

4.1. Therapeutic 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. Posology and method of administration

Oral use

Usual dosage: 1 tablet daily at meal times.

Haemorrhoidal attack: 3 tablets per day for the first 4 days, then 2 tablets per day for 3 days.

4.3. Contraindications

Hypersensitivity to the active substance or to any of the excipients (see section 6.1)

4.4. Special warnings and precautions for use

The administration of this product does not preclude specific treatment for other anal conditions.

If symptoms do not subside promptly, a proctological examination should be performed and the treatment should be reviewed.

4.5. Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed. No clinically relevant drug interaction has been reported to date from post marketing experience on the product.

4.6. Fertility, pregnancy and breastfeeding

Pregnancy

There are no or limited amount of data from the use of Micronised Purified Flavonoid Fraction in pregnant women.
Animal studies do not indicate reproductive toxicity (see section 5.3).
As a precautionary measure, it is preferable to avoid the use of DAFLON during pregnancy.

Breastfeeding

It is unknown whether the active substance/metabolites are excreted in human milk.
A risk to the newborns/infants cannot be excluded.
A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from DAFLON therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility

Reproductive toxicity studies showed no effect on fertility in male and female rats (see section 5.3).

4.7. Effects on ability to drive and use machines

No specific studies on the effects of flavonoid fraction on the ability to drive and use machines have been performed. However, on the basis of the overall safety profile of flavonoid fraction, DAFLON has nor or negligible influence on these abilities.

4.8. Undesirable effects

The following adverse effects have been reported and are classified as a function of their frequency:

Very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1000, <1/100); rare (≥1/10000, <1/1000); very rare (<1/10000), and not known (cannot be estimated from the available data).

Nervous system disorders

Rare effects: dizziness, headaches, malaise.

Gastro-intestinal disorders

Common effects: diarrhoea, dyspepsia, nausea, vomiting.

Uncommon effects: colitis.

Not known: abdominal pain

Skin and subcutaneous tissue disorders

Rare effects: rash, pruritus, urticaria

Not known: isolated face, lip, eyelid oedema. Exceptionally Quincke's oedema

Reporting of side effects
If you experience any undesirable effect, consult your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
You can also declare the undesirable effects directly via the national declaration system.
By reporting side effects, you can help provide more information on the safety of this medicine.

4.9. Overdose

Symptoms

There is limited experience with DAFLON overdose. The most frequently reported adverse events in overdose cases were gastrointestinal events (such as diarrhoea, nausea, abdominal pain) and skin events (such as pruritus, rash).

Management

Management of overdose should consist in treatment of clinical symptoms.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic class: Venotonic and vasculoprotective agent, ATC code: C05CA53

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 1 tablet.

Venotonic activity

DAFLON 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 increases capillary resistance, as measured by angiosterrometry.

5.2. Pharmacokinetic 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.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sodium starch glycolate, orange flavour, microcrystalline cellulose, gelatine, magnesium stearate, talc, titanium, dioxide (E 171), glycerol, sodium lauryl sulphate, macrogol 6000, hypromellose, yellow iron oxide (E 172), red iron oxide (E 172).

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

2 years

6.4. Special precautions for storage

Store below 30°C

6.5. Nature and contents of container

30 film coated tablets in blister packs (PVC-Aluminium).

6.6. Special instructions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

LES LABORATOIRES SERVIER -FRANCE

8. DATE OF REVISION OF THE TEXT

Juanuary 2019