daflon® 1000mg

Micronised purified flavonoid fraction

Presentation and composition

Boxes of 30 film-coated tablets.

Micronized purified flavonoid fraction 1000mg corresponding to:
- diosmin: 90 % (900mg)
- flavonoids expressed as hesperidin: 10 % (100mg)

Excipients q.s. for one tablet

List of excipients: Cellulose microcrystalline, gelatin, magnesium stearate, sodium starch glycolate type A, talc, Macrogol 6000, purified water. Film coating components: Glycerol, hypromellose, macrogol 6000, magnesium stearate, red iron oxide, sodium laurilsulfate, titanium dioxide and yellow iron oxide.

The drug product is a salmon coloured, oblong, film-coated tablet of 23.3 mm in length and 8.3 mm in width, scored on both faces and finished to a mass of 1378 mg.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Therapeutic properties

Vascular protector (it increases resistance in small blood vessels) and venous tonic (it increases venous tone).

Daflon® 1000 is active on the return vascular system in the following way:
- It reduces venous distensibility and venous stasis.
- In the microcirculation, it normalizes capillary permeability and reinforces capillary resistance.

Therapeutic indications

Treatment of acute hemorrhoidal attacks.

Dosage and method of administration

3 tablets daily (in 3 divided doses) for 3 to 4 days, then 2 tablets daily (in 2 divided doses)

Contraindications

Do not take Daflon® 1000 if you are allergic (hypersensitive) to micronized purified flavonoid fraction or any of the other ingredients.

Precautions

Acute hemorrhoidal attack:
If the hemorrhoid symptoms do not disappear within 15 days, you should ask your doctor for advice.

If you are in any doubt, do not hesitate to ask your doctor or your pharmacist for advice.

Interactions with other medicines and other forms of interactions

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy

As a precautionary measure, it is preferable to avoid the use of Daflon® 1000 during pregnancy.

Breast-feeding

Breast-feeding is not recommended for the duration of the treatment, due to the absence of data on the excretion of the medicine into breast milk.

In general, if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, you should always ask your doctor or pharmacist for advice before using a medication.

Effects on ability to drive and use machines

Not applicable.

Possible side effects

Like all medicines, Daflon® 1000 can cause side effects, although not everybody gets them.

They may include:

Common (affects 1 to 10 users out of 100): gastrointestinal side effects (diarrhoea, dyspepsia, nausea, vomiting).

Uncommon (affects 1 to 10 users out of 1,000): Colitis (inflammation of colon).

Rare (affects 1 to 10 users out of 10,000): dizziness, headache, malaise, hypersensitivity of the skin (rash, pruritis, urticaria)

Frequency not known (cannot be estimated from available data): abdominal pain, isolated face, lip, eyelid oedema (swelling).

Exceptionally Quincke's oedema (rapid swelling of tissues such as the face, lips, mouth, tongue or throat that may result in breathing difficulty).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Symptoms and instructions in case of overdose

If you have taken more Daflon® 1000 than you should, contact your doctor or pharmacist immediately.
The experience of overdoses with Daflon® 1000 is limited but reported symptoms include diarrhea, nausea, abdominal pain, pruritus and rash.

Storage conditions

Store at room temperature, below 30ºC. Do not use after the expiry date indicated on the outer packaging.

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Les Laboratoires Servier – France

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