

SUMMARY OF PRODUCT CHARACTERISTICS

ANSM-Updated on: 12/04/2021

1. NAME OF THE MEDICINAL PRODUCT

DAFLON 1000 mg, film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Micronised purified flavonoid fraction	1000 mg
Corresponding to:	
Diosmin: 90 per cent	900 mg
Flavonoids expressed as hesperidin: 10 per cent	100 mg
Mean humidity	40 mg

For one film-coated tablet

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

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

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Treatment of functional symptoms related to acute haemorrhoidal attack.

4.2. Posology and method of administration

Posology

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

Paediatric population

The safety and efficacy of Daflon 1000 mg in children and adolescents under 18 years of age have not been established.

Method of administration

Oral route.

4.3. Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in 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. The treatment must be short-term. If symptoms do not subside rapidly, a proctological examination should be performed and the treatment should be reviewed.

Excipients

DAFLON 1000 mg contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

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

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

4.6. Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of micronised purified flavonoid fraction in pregnant women.

Experimental studies performed in animals have not revealed reproductive toxicity (see section 5.3).

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

Breast-feeding

It is unknown whether the micronised purified flavonoid fraction/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 have shown no effects on female and male 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 the flavonoid fraction, DAFLON has no or negligible influence on the ability to drive and use machines.

4.8. Undesirable effects

The following undesirable effects have been reported and are classified as a function of their frequency.

Very common ($\geq 1/10$); common ($\geq 1/100$, $< 1/10$); uncommon ($\geq 1/1,000$, $< 1/100$); rare ($\geq 1/10,000$, $< 1/1,000$); very rare ($< 1/10,000$), and not known (cannot be estimated from the available data).

Nervous system disorders

Rare: dizziness, headaches, malaise.

Gastrointestinal disorders

Common: diarrhoea, dyspepsia, nausea, vomiting.

Uncommon: colitis.

Unknown frequency: abdominal pain.

Skin and subcutaneous tissue disorders

Rare: rash, pruritus, urticaria.

Unknown frequency: isolated face, eyelid and lips oedema. Exceptionally, Quincke's oedema.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system: French national agency for the

safety of medicines and health products (ANSM) and the network of Regional Pharmacovigilance Centres - Website: www.signalement-sante.gouv.fr.

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 group: VASOPROTECTIVES / CAPILLARY STABILIZING AGENTS / BIOFLAVONOIDS, ATC code: C05CA53.

Pharmacodynamic effects

DAFLON exerts a dual action on the vascular return system:

- at vein and venule level, it increases parietal tone and exerts an anti-stasis action;
- at the microcirculatory level, it reinforces capillary resistance and normalises capillary permeability.

5.2. Pharmacokinetic properties

In humans, following oral administration of the medicinal product with carbon 14-labelled diosmin:

- excretion is essentially faecal and urinary excretion is on average 14% of the administered quantity,
- the elimination half-life is 11 hours,
- the product is highly metabolised, this metabolism is revealed by the presence of different phenol acids in the urine.

5.3. Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of repeated dose toxicity, genotoxicity and toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sodium starch glycolate, microcrystalline cellulose, gelatine, magnesium stearate, talc, purified water.

Film-coating: titanium dioxide (E 171), glycerol, sodium lauryl sulphate, macrogol 6000, hypromellose, yellow iron oxide (E 172), red iron oxide (E 172), magnesium stearate.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

4 years.

6.4. Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5. Nature and contents of container

18, 30, 36 or 40 film-coated tablets in blisters (PVC/Aluminium).

Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

No special requirements for disposal.

7. MARKETING AUTHORISATION HOLDER

LES LABORATOIRES SERVIER
50 RUE CARNOT
92284 SURESNES CEDEX
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

- CIP 34009 300 745 6 5: 18 film-coated tablets in blister packs (PVC/aluminium)
- CIP 34009 550 265 6 3: 30 film-coated tablets in blister packs (PVC/aluminium)
- CIP 34009 550 265 8 7: 36 film-coated tablets in blister packs (PVC/aluminium)
- CIP 34009 550 265 9 4: 40 film-coated tablets in blister packs (PVC/aluminium)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[to be completed by the Marketing Authorisation Holder]

10. DATE OF REVISION OF THE TEXT

[to be completed by the Marketing Authorisation Holder]

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription.

PACKAGE LEAFLET: INFORMATION FOR THE USER

ANSM-Updated on: 12/04/2021

Name of the medicinal product

DAFLON 1000 mg, film-coated tablets.
Micronised purified flavonoid fraction

Boxed text

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What DAFLON 1000 mg, film-coated tablets is and what it is used for
2. What you need to know before you take DAFLON 1000 mg, film-coated tablets
3. How to take DAFLON 1000 mg, film-coated tablets
4. Possible side effects
5. How to store DAFLON 1000 mg, film-coated tablets
6. Contents of the pack and other information

1. WHAT DAFLON 1000 mg, film-coated tablets IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group: VASOPROTECTIVES / CAPILLARY STABILIZING AGENTS / BIOFLAVONOIDS – ATC code: C05CA53

This medicine is a venotonic (it increases venous tone) and a vasculoprotector (it increases resistance in small blood vessels).

It is recommended for the treatment of functional symptoms related to acute haemorrhoidal attack.

If the hemorrhoid symptoms do not disappear within 15 days, it is essential that you consult your doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DAFLON 1000 mg, film-coated tablets

Do not take DAFLON 1000 mg, film-coated tablets:

- If you are allergic to the micronised purified flavonoid fraction or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking DAFLON 1000 mg, film-coated tablets.

Children

Not applicable.

Other medicines and DAFLON 1000 mg, film-coated tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

DAFLON 1000 mg, film-coated tablets with food and drink

Not applicable.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

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

Breast-feeding

In the absence of data in breast-feeding women, it is preferable to avoid breast-feeding while taking this treatment.

Driving and using machines

Not applicable.

DAFLON 1000 mg, film-coated tablets contains sodium

DAFLON 1000 mg contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE DAFLON 1000 mg, film-coated tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 3 tablets daily for 4 days, then 2 tablets daily for the next 3 days at mealtimes.

If you take more DAFLON 1000 mg, film-coated tablets than you should

Contact your doctor or pharmacist immediately.

The experience of overdoses with DAFLON is limited but reported symptoms include diarrhoea, nausea, abdominal pain, pruritus and rash.

If you forget to take DAFLON 1000 mg, film-coated tablets

Not applicable.

If you stop taking DAFLON 1000 mg, film-coated tablets

Not applicable.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The frequency of the possible side effects listed below is defined using the following system:

- very common (affects more than 1 in 10 users)
- common (affects between 1 and 10 in 100 users)
- uncommon (affects between 1 and 10 in 1,000 users)
- rare (affects between 1 and 10 in 10,000 users)
- very rare (affects fewer than 1 in 10,000 users)
- not known (cannot be estimated from the available data)

They may include:

Common: diarrhoea, dyspepsia (difficult digestion), nausea, vomiting.

Uncommon: colitis (inflammation of the large intestine).

Rare: dizziness, headaches, discomfort, rash (sudden redness in patches), pruritus (skin reactions such as itching) and urticaria (allergic reaction in the form of small red spots).

Not known (cannot be estimated from the available data): abdominal pain, isolated oedema (swelling) of the face, lips and eyelids.

Exceptionally: Quincke's oedema (swelling of the face, lips, mouth, tongue or throat which could cause breathing difficulties)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: French national agency for the safety of medicines and health products (ANSM) and the network of Regional Pharmacovigilance Centres - Website: www.signalement-sante.gouv.fr.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DAFLON 1000 mg, film-coated tablets

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box. The expiry date refers to the last day of that month.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What DAFLON 1000 mg, film-coated tablets contains

- The active substance is:

Micronised purified flavonoid fraction 1000 mg

Corresponding to:

Diosmin: 90 per cent 900 mg

Flavonoids expressed as hesperidin: 10 per cent 100 mg

Mean humidity 40 mg

For one film-coated tablet.

- The other ingredients are:

Sodium starch glycolate, microcrystalline cellulose, gelatine, magnesium stearate, talc, purified water.

Film-coating: titanium dioxide (E 171), glycerol, sodium laurylsulphate, macrogol 6000, hypromellose, yellow iron oxide (E 172), red iron oxide (E 172), magnesium stearate.

What DAFLON 1000 mg, film-coated tablets looks like and contents of the pack

Film-coated tablets. Boxes of 18, 30, 36 or 40 film-coated tablets.

Not all pack sizes may be marketed.

Marketing authorisation holder

LES LABORATOIRES SERVIER

50 RUE CARNOT

92284 SURESNES CEDEX

FRANCE

Distributor

LES LABORATOIRES SERVIER

50 RUE CARNOT

92284 SURESNES CEDEX

FRANCE

Manufacturer

LES LABORATOIRES SERVIER INDUSTRIE

905 ROUTE DE SARAN

45520 GIDY

FRANCE

Names of the medicinal product in the Member States of the European Economic Area

Not applicable.

This leaflet was last revised in:

[To be completed subsequently by the marketing authorisation holder]

Other

Detailed information on this medicine is available on the web site of ANSM (France)

Health education advice:

Drink 1.5 to 2 litres of water per day, eat foods that are high in fibre to avoid constipation (fruit, green vegetables, whole grains).

Avoid fats, coffee, alcohol and spicy foods.

Take regular exercise to stimulate the blood flow.

Avoid carrying objects that are too heavy.