daflon® 1000mg Micronized Purified Flavonoid Fraction film-coated tablet

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms
 are the same as yours.
- If any of the side effects gets worse, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

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

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

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

It is recommended for treating:

- Venous circulation disorders (swollen legs, pain, restless legs) and
- Symptoms due to acute hemorrhoidal attack.

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

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

 if you are allergic (hypersensitive) to micronized purified flavonoid fraction, especially diosmin (or hesperidin), or any of the ingredients of this medicine.

Take special care with DAFLON 1000 mg, film-coated tablet:

 if you take this medicine for haemorrhoidal episodes and your problem persists for more than 15 days, it is essential that you consult your doctor.

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.
- if you take this medicine for venous circulation disorders (in particular, sensation of heavy legs), you must also make sure that you:
 - have a healthy lifestyle,
 - avoid exposure to sun, heat,
 - do not remain standing for too long,
 - are not overweight.

Walking, and wearing appropriate stockings or socks, when applicable, promote blood circulation.

Taking or using other medicines

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

Pregnancy and breast-feeding

Pregnancy

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

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.

Ask your doctor or pharmacist for advice before taking this medicine.

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

Posology

Always take DAFLON exactly as your doctor has told you. If you are not sure, you should check with you doctor or pharmacist.

The usual dose is 1 tablet daily at mealtimes.

In the case of haemorrhoidal attack: the usual dose is 3 tablets per day for 4 days and then 2 tablets per day for the next 3 days, at mealtimes.

Method and route of administration

Swallow the tablet with adequate amount of water.

Duration of treatment

Your doctor will tell you how long the treatment will last. Do not stop the treatment without prior consultation to your doctor.

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

If you take more DAFLON 1000 mg, film-coated tablets than you should, contact your doctor immediately.

If you forget to take DAFLON 1000 mg, film-coated tablet Do not take a double dose to make up for a forgotten dose. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, DAFLON 1000 mg, film-coated tablet can cause side effects, although not everybody gets them.

The frequency of the possible undesirable effects listed below is defined according to the following system:

- very common (affects more than 1 user out of 10)
- common (affects 1 to 10 persons out of 100)
- uncommon (affects 1 to 10 persons out of 1,000)
- rare (affects 1 to 10 persons out of 10,000)
- very rare (affects less than 1 user out of 10,000)
- not known frequency (cannot be estimated from the available data)

They may include:

Common: diarrhoea, dyspepsia, nausea, vomiting.

Uncommon: colitis.

Rare: dizziness, headache, malaise, rash, pruritus, urticaria. Not known frequency: Abdominal pain, isolated face, lip, eyelid oedema. Exceptionally Quincke's oedema

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.

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 tablet

Keep this medicine 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.

Store below 30°C.

Store in the original outer packaging.

This medicine does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What DAFLON 1000 mg, film-coated tablet contains The active substances are:

Micronised purified flavonoid fraction	1000	mg
corresponding to:		
Diosmin: 90 percent	900	mg
Flavonoids expressed as hesperidin: 10 percent	. 100	mg
Mean moisture	40	mg
For one film-coated tablet		Ĭ

The other ingredients are:

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

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

What DAFLON 1000 mg, film-coated tablet looks like and content of the pack

10, 18, 30, 36, 40 film-coated tablets in blister (PVC-Aluminium) Not all pack size may be marketed.



LES LABORATOIRES SERVIER, FRANCE

Manufacturer

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