daflon® 500 mg

film-coated tablets
Micronised purified flavonoid fraction

Read all of this leaflet carefully before you start taking this medicine because it contains important information.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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.

In this leaflet:

1. WHAT DAFLON 500 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 500 mg, film coated tablets.

Do not take DAFLON 500 mg, film-coated tablet:
If you are allergic (hypersensitive) to micronised and purified flavonoid fraction, especially diosmin (or hesperidin), or any of the other ingredients in this medicine.

Take special care with DAFLON 500 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.
- if you take this medicine for venous circulation disorders (in particular, sensation of heavy legs), you must also make sure that you:
  - o have a healthy lifestyle,
  - o avoid exposure to sun, heat,
  - o do not remain standing for too long,
  - o are not overweight.

Walking, and wearing appropriate stockings or socks, when applicable, promote blood circulation. At the end of the leaflet more advice is provided for relieving your legs.

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 breastfeeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor of 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
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.

3. HOW TO TAKE DAFLON 500 mg, film-coated tablet

Dose
Always take DAFLON exactly as your doctor has described. If you are not sure, you should check with your doctor or pharmacist.
If you take this medicine for a venous circulation disorders, the usual dose is 2 tablets daily: 1 tablet at midday and 1 tablet in the evening, at mealtimes.
If you take this medicine for a haemorrhoidal episode, the usual dose is 6 tablets per day for 4 days and then 4 tablets per day for the next 3 days.

Method of administration
The tablets must be swallowed with a glass of water.

Frequency of administration
Midday and evening at mealtime.

Duration of treatment
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.

If you have taken more Daflon 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, DAFLON 500 mg, film-coated tablet can cause side effects, although not everyone 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 more 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 500 mg, film-coated tablet

Keep out of the reach and sight of children.
Do not use DAFLON 500 mg, film-coated tablet 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.
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. Contents of the pack and other information

What DAFLON 500 mg, film-coated tablet contains?
The drug substances are:
Micronised, purified flavonoid fraction.....500 mg
quantity corresponding to: Diosmin.....450 mg
Flavonoids expressed as hesperidin.....50 mg
per tablet
The other ingredients are:
Sodium starch glycolate, microcrystalline cellulose, gelatine, magnesium stearate, talc, glycerol, hypromellose, macrogol 6000, sodium laurylsulphate, yellow iron oxide (E 172), red iron oxide (E 172), titanium dioxide (E 171).
What is DAFLON 500 mg, film-coated tablet and contents of the pack ?
10, 30 or 60 film-coated tablets in blister (PVC-Aluminium).
Not all pack sizes may be available.

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