

film-coated tablets
Micronised purified flavonoid fraction

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.

In this leaflet :

1. What DAFLON 500 mg is and what it is used for
2. Before you take DAFLON 500 mg
3. How to take DAFLON 500 mg
4. Possible side effects
5. How to store DAFLON 500 mg
6. Further information

1. WHAT DAFLON 500 mg 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. BEFORE YOU TAKE DAFLON 500 mg

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:
 - 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. 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 breast-feeding

Pregnancy

If you become pregnant during your treatment, or if you are pregnant and

plan to take this medicine, ask your doctor for advice .

Breast-feeding

Breast-feeding is inadvisable for the duration of the treatment, due to the absence of data on the passage of the medicine into breast milk.

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

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 .

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 forget to take DAFLON 500 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 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.

Unknown frequency: abdominal pain, isolated face, lip, eyelid oedema .

Exceptionally Quincke's oedema.

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.

5. HOW TO STORE DAFLON 500 mg, film-coated tablet

Keep out of the reach and sight of children.

Do not use DAFLON 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. FURTHER 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 (E172), red iron oxide (E172), titanium dioxide (E171).

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.

This leaflet was updated in July 2016

Packaging authorization holder and batch releaser:

Rougine Darou – Iran

Under license of Les Laboratoires Servier - France

Manufacturer of the bulk tablets:

Les Laboratoires Servier Industrie - 45520 Gidy - France

Packaging site :Amin Pharmaceutical Co