PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

DAFLON 500 mg, film-coated tablet
Micronized purified flavonoid fraction

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 has 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 after

What is in this leaflet:

1. WHAT DAFLON 500 mg IS AND WHAT IT IS USED FOR

DAFLON 500 mg 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 for treating symptoms due to acute hemorrhoidal attack.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DAFLON 500 mg

Do not take DAFLON 500 mg
If you are hypersensitive (allergic) to micronised purified flavonoic fraction or any of the other ingredients of this medicine.

Take special care with DAFLON 500 mg
Acute hemorrhoidal attack:
If the hemorrhoid symptoms do not disappear within 15 days, you should ask your doctor for advice.
Venous circulation disorders:
The most effective way of taking this treatment is in combination with a healthy lifestyle.
Avoid exposure to the sun, heat, excessive standing and being overweight. Walking and wearing special support stockings stimulate blood circulation.

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

Taking other medicines
No cases of interaction have been reported during treatment with DAFLON 500 mg.
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think that 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 on excretion in milk, DAFLON 500 mg is not recommended during breast-feeding.

Driving and using machines
DAFLON 500 mg has no influence on the ability to drive or use machines.

3. HOW TO TAKE DAFLON 500 mg

Always use this medicine exactly as described in this leaflet or how pharmacist has told you. Check with your pharmacist if you are not sure.

Oral route.

The tablets should be taken at meal times.

Venous insufficiency: 2 tablets daily, one at midday and one in the evening.

Acute hemorroidal attack: a 4-day course of 6 tablets daily, followed by 4 tablets daily over the next 3 days.

If you take more DAFLON 500 mg than you should
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.

If you forget to take DAFLON 500 mg
If you forget to take a dose, take the next dose at the usual time. 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 can cause side effects, although not everybody gets them.

These side effects include:
- Commonly (less than 1 per 10 but more than 1 per 100): gastro-intestinal disorders (diarrhea, indigestion, nausea, vomiting).
- Uncommonly (less than 1 per 100 but more than 1 per 1000): colitis.
- Rarely (less than 1 per 1000 but more than 1 per 10,000): neurovegetative disorders (dizziness, headache, malaise) and skin reactions (rash, pruritus, urticaria).
- Frequency not known: 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).

These side effects have been reported, not requiring discontinuation of treatment.

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.

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

Malta:
ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

Cyprus:
Pharmaceutical Services
Ministry of Health
CY-1475 Nicosia
Fax: + 357 22608649
website: www.moh.gov.cy/phs

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

5. HOW TO STORE DAFLON 500 mg

Keep out of the reach and sight of children.

Store below 30°C.

Do not use DAFLON 500 mg after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What DAFLON 500 mg contains

- The active substance is Micronized purified flavonoid fraction 500 mg corresponding to Diosmin (90 %) 450 mg and Flavonoids expressed as hesperidin (10 %) 50 mg for a film-coated tablet.
- The other ingredients are: gelatin, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, talc for the tablet core; glycerol, macrogol 6000, magnesium stearate, methylhydroxypropylcellulose, red iron oxide (E172), sodium lauryl sulfate, titanium dioxide, yellow iron oxide (E172) for the film-coating.

What DAFLON 500 mg looks like and contents of the pack
DAFLON 500 mg tablets are film-coated.
The tablets are available in blister packed in cartons of 30, 36, 60, 120 and 180 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder and Exceptional Marketing Authorisation Holder:
Les Laboratoires Servier
50, rue Carnot
92284 Suresnes cedex – France

Local representative in Malta:
V.J. Salomone Pharma Ltd
Tel: + 356 21 22 01 74

Local representative in Cyprus:
C.A. Papaellinas Ltd, PO Box 24018, 1700 Latsia, Nicosia

Manufacturer:
Les Laboratoires Servier Industrie
905, route de Saran
45520 Gidy
France

This leaflet was last approved in October 2022.