

Package leaflet: Information for the patient

DAFLON[®] 500 mg

film-coated tablet
Micronized purified flavonoid fraction

ڈیفلون[®] ۵۰۰ ملی گرام
مائیکرونائیزڈ پوریفائیڈ فلویونائیڈ فرائکشن

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 serious, 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, film-coated tablet IS AND WHAT IT IS USED FOR
2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DAFLON 500 mg, film-coated tablet
3. HOW TO TAKE DAFLON 500 mg, film-coated tablet
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE DAFLON 500 mg, film-coated tablet
6. FURTHER INFORMATION

1. WHAT DAFLON 500 mg, film-coated tablet IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group

Medicinal product acting on the capillaries
Cardiovascular system

Therapeutic indications

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 (heavy legs, pain, restless legs) and functional signs related to haemorrhoidal attack.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DAFLON 500 mg, film-coated tablet

List of information necessary before taking the medicinal product
Not applicable.

Contraindications

Do not take DAFLON 500 mg, film-coated tablet:

If you are allergic (hypersensitive) to micronized purified flavonoid fraction or any of the other ingredients.

Precautions for use; special warnings

Take special care with DAFLON 500 mg, film-coated tablet:

Haemorrhoidal attack:

If the haemorrhoid disorder persists for more than 15 days, it is essential that you consult your doctor.

Venous circulation disorders:

This treatment is at its most effective when combined with a healthy lifestyle.

- Avoid exposure to the sun, heat, standing for too long, excess weight.
- Walking, and wearing appropriate stockings when applicable, promote blood circulation.

Interaction with other medicinal products

Taking or using other medicines:

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

Interactions with food and drink

Not applicable.

Interaction with herbal therapy products or alternative therapies

Not applicable.

Use during 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

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.

Sports

Not applicable.

Effects on the ability to drive and use machines

Not applicable.

List of exipients with a known effect

Not applicable

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

Instructions for a correct use

Not applicable.

Posology, Method and/or route(s) of administration, Frequency of administration and Duration of treatment

Dosage

Venous insufficiency: 2 tablets daily, 1 tablet at midday and 1 tablet in the evening, at mealtimes.

Haemorrhoidal attack: the dose is 6 tablets per day for 4 days and then 4 tablets per day for the next 3 days, at mealtimes.

Symptoms and instructions in case of overdose

If you have taken more DAFLON 500 mg, film-coated tablet 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.

Instructions in case of omission of one or more doses

Not applicable.

Risk of withdrawal syndrome

Not applicable.

4. POSSIBLE SIDE EFFECTS

Description of side effects

Like all medicines, DAFLON 500 mg, film-coated tablet can cause side effects, although not everybody gets them.

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

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

They may include:

Common: diarrhoea, dyspepsia, nausea, vomiting.

Uncommon: colitis.

Rare: dizziness, headaches, discomfort, rash, itching, urticaria.

Frequency not known: 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 to Drug Regulatory Authority of Pakistan via www.dra.gov.pk. 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.

Expiry date

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.

Storage conditions

No special storage conditions

If necessary, warnings about certain visible signs of deterioration

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

Full list of active substances and excipients

What DAFLON 500 mg, film-coated tablet contains

The active substances are:

Micronized purified flavonoid fraction 500.000 mg
Corresponding to:
Diosmin: 90 per cent 450.000 mg
Flavonoids expressed as hesperidin: 10 per cent 50.000 mg
Mean moisture 20.000 mg
For one film-coated tablet

The other ingredients are:

Sodium starch glycolate, microcrystalline cellulose, gelatine, magnesium stearate, talc.
Film-coating: titanium dioxide (E 171), glycerol, sodium laurylsulphate, macrogol 6000, hypromellose, yellow iron oxide (E 172), red iron oxide (E 172), magnesium stearate.

Pharmaceutical form and contents

What DAFLON 500 mg, film-coated tablet looks like and contents of the pack

This medicinal product is supplied in the form of film-coated tablets. Boxes of 20 film-coated tablets.

Manufacturer and Marketing Authorization Holder

Servier Research & Pharmaceuticals [Pakistan] (Pvt) Ltd
9-Km Sheikhupura Road Lahore Pakistan

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