

# diosmin+hesperidin

## daflon<sup>®</sup> 500

450 mg / 50 mg film-coated tablet  
Vasoprotective

### Formulation

Each film-coated tablet contains 500mg MPFF (Micronized purified flavonoid fraction) equivalent to 450mg diosmin and 50mg hesperidin.

### Action

Venotonic/vasculoprotective.

### Indication

Daflon 500 is recommended for treating venous circulation disorders (swollen legs, pain, nocturnal cramps) and for treating symptoms due to acute hemorrhoidal attack.

### Contraindications

Hypersensitivity to the active substance or to any of the excipients.

### Precautions

#### *Hemorrhoidal attack*

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

The administration of this product does not preclude treatment for other anal conditions. The treatment must be short-term.

If symptoms do not subside promptly, a proctological examination should be performed and the treatment should be reviewed.

#### *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.

### 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 or pharmacist for advice before taking this medicine.

#### Pregnancy

There are no or limited amount of data from the use of Micronized Purified Flavonoid Fraction in pregnant women.

Animal studies do not indicate reproductive toxicity.

As a precautionary measure, it is preferable to avoid the use of Diosmin + Hesperidin (Daflon 500) during pregnancy.

#### Breastfeeding

It is unknown whether the active substance/ metabolites are excreted in human milk. A risk to the newborns/infants cannot be excluded. A decision must be made whether to discontinue breastfeeding or to discontinue/abstain from Diosmin + Hesperidin (Daflon 500) therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

### Dosage and administration

Oral route. The tablets should be taken at meal times.

#### *Venous insufficiency*

2 tablets daily, one at mid-day and one in the evening.

#### *Acute hemorrhoidal attack*

A 4-day course of 6 tablets daily, followed by 4 tablets daily over the next 3 days.

In all cases, strictly comply with your doctor's prescription.

### **Possible side effects**

Like all medicines, Diosmin + Hesperidin (Daflon 500) can cause side effects, although not everybody gets them. 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.

Diosmin + Hesperidin (Daflon 500) is usually well tolerated.

The following side effects can appear:

Common (less than one out of 10, but more than one out of 100 users): diarrhea, dyspepsia, nausea, vomiting.

Uncommon (less than one out of 100, but more than one out of 1,000 users): colitis (inflammation of colon).

Rare (less than one out of 1,000, but more than one out of 10,000 users): dizziness, headache, malaise, rash, pruritus, urticaria.

Frequency not known: abdominal pain, isolated face, lip, eyelid edema (swelling). Exceptionally, Quincke's edema (rapid swelling of tissues such as the face, lips, mouth, tongue or throat that may result in breathing difficulty).

### **Reporting of adverse drug reaction**

For suspected adverse drug reaction, report to the FDA at [www.fda.gov.ph](http://www.fda.gov.ph).

Seek medical attention immediately at the first sign of any adverse drug reaction.

### **Interactions with other medications**

You must always tell your doctor or pharmacist about any other treatment you are receiving.

No interaction studies have been performed. No clinically relevant drug interaction has been reported to date from post marketing experience on the product.

### **Overdose**

#### Symptoms

There is limited experience with Diosmin + Hesperidin (Daflon 500) overdose. The most frequently reported adverse events in overdose cases were gastrointestinal events (such as diarrhea, nausea, abdominal pain) and skin events (such as pruritus, rash).

#### Management

Management of overdose should consist in treatment of clinical symptoms.

If you have taken more Diosmin + Hesperidin (Daflon 500) than you should, contact your doctor or pharmacist immediately.

### **Presentation**

Box of 30 tablets x 500mg.

### **Storage condition**

Store at temperatures not exceeding 30°C.

Les Laboratoires Servier-France



### **Manufactured by:**

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

### **Imported by:**

SERVIER PHILIPPINES, INC.  
Unit AD, 11F, 8 Rockwell  
Hidalgo Drive, Rockwell Center, Brgy.  
Poblacion, Makati, Metro Manila

### **Distributed by:**

Zuellig Pharma Corporation  
Km. 14 West Service Road,  
South Super Highway cor. Edison Ave.,  
Sun Valley, Parañaque City

Reg. No.: DR-XY12979

Date of Renewal of the Authorization:

31 August 2016

Date of Revision of this Patient Information  
Leaflet: 22 June 2020