

## PACKAGE LEAFLET

Name of the medicinal product

**daflon<sup>®</sup> 500mg**  
**達夫隆**

film-coated tablet

Micronised purified flavonoid fraction

### Boxed text

**Read all of this leaflet carefully before you start taking this medicine. It contains important information for your treatment.**

If you have any further questions, if you are in any doubt, ask your doctor or pharmacist for more information.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If the symptoms get worse or persist, consult a doctor.
- 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.

### Leaflet contents

#### **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 micronised 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, can 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 500 mg, film-coated tablet 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 excipients 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 take more DAFLON 500 mg, film-coated tablet than you should:**

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 500 mg, film-coated tablet 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 [http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical\\_trade/adr\\_reporting/adr\\_report\\_form\\_electronic.html](http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/adr_reporting/adr_report_form_electronic.html). 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:**

Micronised 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

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 10 and 30 film-coated tablets.

#### **Name and address of the manufacturer and local contact**



*Manufacturer :*  
**LES LABORATOIRES SERVIER INDUSTRIE**  
905, route de Saran  
45520 Gidy  
France

*Local contact :*

*Servier Hong Kong Ltd.  
Room 4201-4203, 42/F.,  
Sunlight Tower,  
248 Queen's Road East,  
Wanchai,  
Hong Kong.  
Tel: (852) 2577 1922*

## HEALTH EDUCATION ADVICE

### **Circulation disorders**

Avoid standing or sitting for prolonged periods, raise the foot of your bed slightly.



Avoid exposure to the sun or to heat



Ensure that you eat a healthy balanced diet and carry out regular physical activity (walking, cycling...), avoid excess weight.



Avoid clothes that are too tight, wear socks or support stockings and rinse legs with cold water to promote blood circulation.

### **Haemorrhoids**

Drink 1.5 to 2 L of water per day, eat foods that are high in fibre to avoid constipation (fruit, green vegetables, whole grains), avoid fats, coffee, alcohol and spicy foods.



Take regular exercise to stimulate the blood flow, and avoid carrying objects that are too heavy.

藥物名稱

# daflon<sup>®</sup> 500mg

## 達夫隆

微粒化、純化黃酮類包衣片劑

服用此藥物前，請詳細閱讀此產品說明書。它包含了有關你治療上的重要訊息。

如你有任何問題或疑問，請向你的醫生或藥劑師查詢。

- 請保留此說明書。你或會有需要再閱讀。
- 如需進一步資訊或建議，請向藥劑師查詢。
- 如症狀轉差或持續，請諮詢醫生。
- 如任何不良反應轉差，或出現任何沒有列於此說明書的不良反應，請告知你的醫生或藥劑師。

說明書內容

**此說明書包括：**

1. 甚麼是 DAFLON<sup>®</sup> 500mg 包衣片劑及其作用
2. 服用 DAFLON<sup>®</sup> 500mg 包衣片劑前須知
3. 怎樣服用 DAFLON<sup>®</sup> 500mg 包衣片劑
4. 可能出現的不良反應
5. 怎樣儲存 DAFLON<sup>®</sup> 500mg 包衣片劑
6. 更多資訊

1. 甚麼是 DAFLON<sup>®</sup> 500mg 包衣片劑及其作用

**藥物治療組別**

心血管系統類：用於微絲血管的藥物

**治療適應症**

此藥物具有靜脈張力調節（增加靜脈張力）及血管保護（增強微細血管抵抗力）作用。

建議用於治療靜脈循環紊亂（腿部沉重、疼痛、腿部不適）及急性痔患發作有關的各種症狀。

2. 服用 DAFLON<sup>®</sup> 500mg 包衣片劑前須知

**服藥前資訊表**

不適用。

**禁忌**

**不要服用 DAFLON<sup>®</sup> 500mg 包衣片劑：**

對微粒化、純化黃酮類和任何其他成份過敏者禁用。

## **注意事項**

服用 DAFLON® 500mg 包衣片劑要特別小心：

### **急性痔患**

如痔患症狀持續超過 15 天，必須諮詢醫生。

### **靜脈循環紊亂**

當配合健康生活模式，此藥物可達至最佳效果。

- 避免陽光、熱力、長時間站立、超重
- 步行、有需要時穿著合適襪褲可增加血液循環

## **藥物相互作用**

### **同時服用其他藥物**

如果你正服用或不久前曾服用其他藥物，包括非處方藥物，請告知你的醫生或藥劑師。

### **食物或飲品相互作用**

不適用。

### **草藥治療產品或替代療法相互作用**

不適用。

## **孕婦及哺乳期用藥**

如果你正在懷孕或哺乳，懷疑自己已懷孕或計劃有小孩，服用此藥前，請向你的醫生或藥劑師查詢。

### **妊娠**

以策安全，懷孕期避服 DAFLON® 500mg 包衣片劑。

### **哺乳**

尚無本藥品分泌至母乳的資料，哺乳期婦女應避免使用本藥。

### **體育運動**

不適用。



### **對駕駛和機械操作能力的影響**

不適用。

### **有已知效應的輔料列表**

不適用。

## **3. 怎樣服用 DAFLON® 500mg 包衣片劑**

### **正確使用指示**

不適用。

### **服用方法，服用途徑，服用次數及治療持續時間 劑量**

靜脈功能不全 - 每日兩片，中午及晚上各一片，飯後服。

急性痔患 - 首四日每日服六片，隨後三日每日服四片，飯後服。

### **服用過量的徵狀及指引**

如服用過量 DAFLON® 500mg 包衣片劑，你應該：

如服用過量 DAFLON® 500mg 包衣片劑，請立即聯絡你的醫生或藥劑師。

雖然過量 DAFLON® 500mg 包衣片劑的經驗有限，不過有紀錄的徵狀包括肚瀉、噁心、腹痛、瘙癢及出疹。

### **忘記服藥指引**

不適用。

### **停藥綜合症風險**

不適用。

## **4. 可能出現的不良反應**

### **不良反應的描述**

和所有藥物一樣，DAFLON® 500mg 包衣片劑可引至不良反應，但不是每個人都會受影響。

按照不良反應的發生率分類如下：很常見 ( $\geq 1/10$ )；常見 ( $\geq 1/100 \sim < 1/10$ )；不常見 ( $\geq 1/1,000 \sim < 1/100$ )；罕見 ( $\geq 1/10,000 \sim < 1/1,000$ )；極罕見 ( $< 1/10,000$ )；未知（從現有資料中很難估計）。

不良反應包括：

- 常見：腹瀉、消化不良、噁心、嘔吐
- 不常見：結腸炎
- 罕見：頭暈、頭痛、不適、皮疹、痕癢症、蕁麻疹
- 未知：腹痛、單獨出現的面部、唇和眼瞼水腫，特殊情況下血管神經性水腫

**呈報不良反應：**

如出現任何不良反應，請向你的醫生或藥劑師查詢。這包括任何在此沒有列出的不良反應。

你也可以透過以下途徑呈報不良反應：

[http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical\\_trade/adr\\_reporting/adr\\_report\\_form\\_electronic.html](http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/adr_reporting/adr_report_form_electronic.html)

將不良反應呈報，你可助提供更多有關這藥物的安全資訊。

## 5. 怎樣儲存 DAFLON® 500mg 包衣片劑

勿放於兒童可觸及可見到的地方。

**到期日**

到期日印於盒上，切勿服用已過期的藥物。到期日是指當月的最後一天。

**儲存條件**

沒有特別的儲存措施。

**如有需要，藥物損毀警示**

藥物不要棄置於污水或家中垃圾。為了保護環境，請向藥劑師查詢如何棄置不再需要的藥物。

## 6. 更多資訊

所有活性成份及輔料

每片包衣片劑含有：

活性成份如下：

Micronised purified flavonoid fraction .....500.00 mg

相等於:

Diosmin: 90 percent .....450.00 mg

Flavonoids expressed as hesperidin: 10 percent ..... 50.00 mg

其他成份如下:

Sodium starch glycolate, microcrystalline cellulose, gelatine, magnesium stearate, talc.

包衣成分: titanium dioxide (E 171), glycerol, sodium lauryl sulphate, macrogol 6000, hypromellose, yellow iron oxide (E 172), red iron oxide (E 172), magnesium stearate.

藥物形式及包裝

此藥物是包衣片劑。每盒 10 或 30 片包衣片劑。

製造商及本地聯絡

製造商 :



**LES LABORATOIRES SERVIER INDUSTRIE**

905, route de Saran

45520 Gidy

France

本地聯絡:

法國施維雅藥廠香港有限公司

香港灣仔皇后大道東 248 號

陽光中心 42 樓 4201-4203 室

電話: (852) 2577 1922

## 健康教育建議

### 循環系統紊亂

避免長時間站立或坐下，睡覺時把雙腳輕微提升。



避免於太陽下曝曬或過熱。



確保均衡飲食及定時運動（步行、騎單車...），避免超重。



避免緊身衣服，穿著壓力襪褲及用冷水沖洗腳部以促進血液循環。

### 痔患



每天喝 1.5 – 2 公升水，進食高纖食物防止便秘（水果、綠色蔬菜、全穀類食物）、避免脂肪，咖啡，酒精及辛辣食物。

定期運動促進血流量，及避免攜帶過重物件。