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English Leaflet

Submitted PIL

(Under evaluation- Ref.# 13648
dated 17/05/1435)

Patient Information Leaflet (PIL)

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

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, health care provider 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 or health care provider.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider 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

- Pharmacotherapeutic group:

Medicinal product acting on the capillaries

C: 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 (swollen legs, pain, early morning restless legs) and for treating symptoms due to acute haemorrhoidal attack.

2. Before you take Daflon 500 mg

a. Do not take Daflon 500mg

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

b. Take special care with Daflon 500 mg

Haemorrhoidal attack:

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

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.

c. Taking or using other medicines, herbal or dietary supplements

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

d. Taking Daflon 500 mg with food and drink

Not applicable.

e. Pregnancy and breastfeeding

Pregnancy

If you discover that you are pregnant during your treatment, or if you are pregnant and plan to take this medicine, ask your doctor or health care provider 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, health care provider or pharmacist for advice before taking any medicine.

f. Driving and using machines

Not applicable.

g. Important information about some of the ingredients of Daflon 500mg

Not applicable.

3. How to take Daflon 500 mg

Always take Daflon 500mg exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider or pharmacist if you are not sure.

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.

a. If you take more Daflon 500 mg than you should

An overdose of this medicine can make side effects worse.

If you take more Daflon 500 mg tablet than you should, contact your doctor, health care provider or pharmacist.

b. If you forget to take Daflon 500mg

Not applicable.

c. If you stop taking daflon 500mg

Not applicable.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Daflon 500 mg can cause side effects, although not everybody gets them.

Some cases of commonplace gastrointestinal disorders and neurovegetative disorders (feeling of discomfort) have been described, which do not require stopping the treatment.

Reporting of side effects

If you get any side effects, talk to your doctor, health care provider or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. 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. Store in the original carton.

Do not use Daflon 500 mg after the expiry date which is stated on the box. 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 protect the environment.

6. FURTHER INFORMATION

a. What Daflon 500 mg 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
Average moisture content.....	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.

b. What is Daflon 500 mg looks like and content of the pack

This medicinal product is supplied in the form of film-coated tablets. Boxes of 30 film-coated tablets.

c. Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Les Laboratoires Servier
50, rue Carnot
92284 SURESNES Cedex
France

Manufacturer

Les Laboratoires Servier Industrie
905, Route de Saran
45520 GIDY
France

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

Saudi Arabia

Les Laboratoires Servier Scientific Office
Al-Sulaimaniah, Al-Safwah building
Riyadh, Saudi Arabia.
Tel: +966 (11) 2886813
E-mail: fawaz.al-anazi@sa.netgrs.com

Gulf Countries

Les Laboratoires Servier Scientific Office
P.O. Box 1586, API Towers Office # 801
Sheikh Zayed Road, Dubai, UAE
Tel: +971 4 3329903
E-mail: magdy.abdou@ae.netgrs.com

d. This leaflet was last revised in 11.2013

e. To report any side effect(s):

- **Saudi Arabia:**

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| <ul style="list-style-type: none">- National Pharmacovigilance Center (NPC)- Fax: +966-11-205-7662- Call NPC at +966-11-2038222, Exts:2317-2356-2353-2354-2334-2340.- Toll free phone: 8002490000- E-mail: npc.drug@sfd.gov.sa- Website: www.sfd.gov.sa/npc |
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- **Other GCC states:**

- Please contact the relevant competent authority.

f. Council of Arab Health Ministers:

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow the doctor's prescription, the method of use and the instruction of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourselves interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

g. This patient information leaflet is approved by the Saudi Food and Drug Authority

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.

Current PIL

daflon[®] 500mg

Micronized purified flavonoid fraction

1. IDENTIFICATION OF THE MEDICINAL PRODUCT

a. Name: DAFLON 500 mg, Micronized purified flavonoid fraction corresponding to:

- diosmin: 90 %
 - flavonoids expressed as hesperidin: 10 %
- Film-coated tablets

b. Statement of the active ingredients and excipients: diosmin: 90 % and flavonoids expressed as hesperidin: 10 % for one film-coated tablet; *Excipients:* sodium carboxymethyl starch, microcrystalline cellulose, gelatin, magnesium stearate, talc, glycerol, hydroxypropylmethyl cellulose, polyoxyethylene glycol 6000, sodium laurylsulphate, yellow iron oxide, red iron oxide, titanium dioxide.

c. Pharmaceutical form and contents: box of 30 film-coated tablets.

d. Pharmacotherapeutic group: vasculoprotector (C: Cardiovascular system).

e. Name and address of the marketing authorization holder

Les Laboratoires Servier
22 rue Garnier
92200 Neuilly sur Seine - France

Manufacturer:

Les Laboratoires Servier Industrie
45520 Gidy – France

2. 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 (swollen legs, pain, restless legs) and for treating symptoms due to acute hemorrhoidal attack.

3. TAKE CARE !

a. Contra-indications: IF IN DOUBT, YOU MUST ASK YOUR PHYSICIAN OR YOUR PHARMACIST FOR ADVICE

b. Precautions for use: 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 giving 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 doubt, do not hesitate to ask your doctor or your pharmacist for advice.

c. Drug interactions and other interactions: In order to avoid possible interactions between various drugs, you must always tell your doctor or your pharmacist about any other treatment you are receiving.

d. Special warnings:

- PREGNANCY AND BREAST-FEEDING

Inform your doctor if you become pregnant.

In the absence of data on entering breast milk, breast-feeding should be avoided during treatment.

In general, if you are pregnant or breast-feeding, you should always ask your doctor or pharmacist for advice before using a medication.

THIS IS A MEDICAMENT

Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

Follow the doctor's prescription, the method of use and the instruction of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourselves interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
UNION OF ARAB PHARMACISTS

4. USUAL INSTRUCTIONS FOR PROPER USE

a. DOSAGE: Venous insufficiency: 2 tablets daily, one at midday 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.

b. METHOD AND ROUTE OF ADMINISTRATION: Oral route.

c. FREQUENCY AND TIME AT WHICH THE DRUG SHOULD BE TAKEN: Comply with your doctor's prescription. The tablet should be taken at meal times.

TREATMENT DURATION: Comply with your doctor's prescription.

5. UNDESIRABLE EFFECTS

Some cases of routine gastric disorders and neurovegetative disorders (feeling of discomfort) have been reported, not requiring discontinuation of treatment.

Report any untoward or undesirable effect which has not been mentioned in this package insert to your doctor or your pharmacist.

6. STORAGE

a. DO NOT USE AFTER THE EXPIRY DATE INDICATED ON THE OUTER PACKAGING.

b. SPECIAL STORAGE PRECAUTIONS: store below 30°C

7. PACKAGE INSERT REVISION DATE

March 2000



Les Laboratoires Servier - France
Manufacturer:
Les Laboratoires Servier Industrie
45520 Gidy - France