

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### PHLEBODIA

600mg Tablets

DIOSMIN

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• 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 only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

1. What PHLEBODIA is and what it is used for
2. Before you take PHLEBODIA
3. How to take PHLEBODIA
4. Possible side effects
5. How to store PHLEBODIA
6. Further information

#### 1. WHAT PHLEBODIA IS AND WHAT IS IT USED FOR

VASCULOPROTECTIVE / DRUG ACTING ON CAPILLARIES  
(C05CA03: cardiovascular system).

This drug is a venotonic (it increases the tonus of venous walls) and a vasculoprotective (it increases the resistance of the small blood vessels).

It is preconised in:

- Venous circulation troubles (heavy legs, pain, restlessness when lying down).
- Treatment of functional signs related to acute haemorrhoids.

#### 2. BEFORE YOU TAKE PHLEBODIA

##### **Do not use PHLEBODIA**

This drug is generally not recommended during lactation.

##### **Take special care with PHLEBODIA**

- If troubles and fragility of blood vessels do not decrease within 15 days, consult your doctor.

- If haemorrhoidal symptoms persist after some days of treatment, it is necessary to consult your doctor.

#### ***Precautions for use***

- This drug has the maximal efficiency when associated to healthy habits.
- Avoid sun, warmth, prolonged standing, excess of weight. Walking and wearing appropriated stockings improve the blood circulation.
- This medicinal product contains an azoic agent, the cochineal red A (E 124), and could induce allergic reactions.

#### ***Taking other medicines***

In order to avoid drug interactions between several drugs indicate systematically all current treatment to your doctor or your pharmacist.

#### ***Taking PHLEBODIA with food and drink***

Not applicable.

#### ***Taking PHLEBODIA with products of herbal medicine or alternative therapies***

Not applicable

#### ***Pregnancy and breast-feeding Pregnancy:***

This drug will be used during pregnancy only if necessary, according to your doctor's advice. If you discover that you are pregnant during the treatment ask your doctor because he can judge if it is necessary to go on with this treatment.

#### ***Lactation:***

In the absence of data concerning passage into breast milk, the treatment is not recommended during lactation.

Ask your doctor or pharmacist for advice before taking any medicine.

#### ***Sportmen or women***

Not applicable

#### ***Driving and using machines***

Not applicable.

#### ***Important information about some of the ingredients of PHLEBODIA***

List of excipients which have to be well known to ensure the risk-free use of this drug: cochineal Red A (E124).

### ***3. HOW TO TAKE PHLEBODIA***

#### **Dosage**

- Venous circulation troubles: 1 tablet per day, in the morning before breakfast.
- Acute haemorrhoids: 2 to 3 tablets per day, to be taken during meals.

IN ALL CASES, RESPECT YOUR DOCTOR'S PRESCRIPTION.

**Way of use and route of administration** Oral administration.

Swallow the tablet with a glass of water.

**Frequency and time when the drug must be taken**

IN ALL CASES, RESPECT STRICTLY YOUR DOCTOR'S PRESCRIPTION.

**Duration of treatment**

IN ALL CASES, RESPECT STRICTLY YOUR DOCTOR'S PRESCRIPTION

***If you take more PHLEBODIA than you should***

Not applicable.

***If you forget to take PHLEBODIA***

Do not take a double dose to make up for a forgotten tablet.

***If you stop taking PHLEBODIA***

Not applicable

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, PHLEBODIA can cause side effects, although not everybody gets them: possibility of minor digestive troubles leading rarely to stop the treatment.

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

**5. HOW TO STORE PHLEBODIA**

Keep out of the reach and sight of children.

Do not use PHLEBODIA after the expiry date which is stated on the label.

No particular precautions of storage.

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. FURTHER INFORMATION**

***What PHLEBODIA contains ?*** The active substance is :

Diosmin (expressed in anhydrous and pure diosmin) ..... 600 mg. For a tablet

The other ingredients are:

Talc, hydrophobic anhydrous colloidal silica, micronized stearic acid, microcrystalline cellulose.

Coating : hypromellose , microcrystalline cellulose , macrogol 8 stearate, propylene glycol, titanium dioxide, Cochineal red A - aluminium lake, black iron oxide , red iron oxide , carnauba wax , beeswax, shellac , ethanol 95 %.

***What PHLEBODIA looks like and contents of the pack ?***

The pharmaceutical form is tablet.

The immediate packaging consists of a blister pack containing 15 and 30 coated tablets.

***Marketing Authorisation Holder***

Laboratoires INNOTHERA, 22 Avenue Aristide Briand, 94110 ARCUEIL, FRANCE

***Manufacturer***

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