FLUXON™ 500

Microcrystalline Purified Flavonoid Fraction (MPFF)

[DIOSMIN MPFF]

Coated Tablets
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Characteristics and advantages

Why DIOSMIN MPFF differs from ordinary diosmins?

Diosmin MPFF with its extraordinarily expanded specific surface area (over 8 m²/g) enhances the drug wettability and leads to a faster absorption.

Diosmin MPFF shows fast wettability and greater absorption rate than ordinary diosmin and exhibit a superior clinical efficacy in treating venous diseases.

Diosmin MPFF presents a favourable ratio of Diosmin/Flavonoid substances, expressed as hesperidin, and contains concomitantly flavonoids such as isorhoifolin, linarin, diosmetin and thus favours the prompt relief to the pathophysiological conditions.
An unique and advantageous mode of action, fighting simultaneously the multiple pathophysiological aspects of the venous disease, affecting the veins, lymphatics, and microcirculation.

**FLUXON™ 500** prolongs the vasoconstrictor effect of noradrenaline on the vein wall, increasing venous tone, and therefore reducing venous capacitance, distensibility, and stasis.

**FLUXON™ 500** improves venous return and reduces venous hyperpressure present in chronic venous disease conditions.
**FLUXON™ 500** enhances lymphatic drainage by increasing the frequency and the intensity of lymphatic contractions, and decreases the diameter of lymphatic capillaries and the intralymphatic pressure.

**FLUXON™ 500** reduces capillary hyperpermeability and increases capillary resistance by protecting the microcirculation from damaging processes.

**FLUXON™ 500** reduces the expression of certain adhesion molecules on endothelial cells and on leukocytes, leading to a reduction in the release of inflammatory mediators, especially oxygen free radicals and prostaglandins.

**FLUXON™ 500** presents a restorative and protective efficacy in chronic venous disease and hemorrhoidal disease, both of which are associated with perivascular inflammation and edema.
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COMPOSITION

Each coated tablet containing:

Active ingredient: Microcrystalline Purified Flavonoid Fraction 500 mg (diosmin 450 mg/tablet and flavonoids expressed as hesperidin 50 mg/coated tablet).

Excipients: microcrystalline cellulose, gelatine vegetable, sodium starch glycolate, hydroxypropyl methyl cellulose, talc, magnesium stearate, titanium dioxide, polyethylene glycol, glycerin, sodium lauryl sulfate, yellow iron oxide E172, red iron oxide E172.

PHARMACEUTICAL FORM AND CONTENTS

Coated tablet dosed at 500 mg of diosmin MPFF.

PHARMACOTHERAPEUTIC CLASS

Vascular protector and venotonic (ATC code: C05CA03).

HOLDER OF MARKETING AUTORISATION

As applicable.

MANUFACTURER AND FINAL CONTROLLER

Coated tablet. As applicable.

THERAPEUTIC INDICATIONS

- Treatment of organic and idiopathic chronic venous disease of the lower limbs for relief of the following symptoms: heavy legs, pain, nocturnal cramps, edema.
- Treatment of hemorrhoids and acute hemorrhoidal attacks.
CONTRAINdicATIONS

Hypersensitivity to active ingredient or to excipients.

PRECAUTIONS

Pregnancy: experimental studies in animal have not demonstrated any teratogenic effects and no harmful effects have been reported in man to date.
Lactation: in the absence of data concerning the diffusion into breast milk, breast-feeding is not recommended during treatment.

INTERACTIONS

None.

SPECIAL WARNINGS

None.

Effects on ability to drive and use machines
The product does not interfere with the ability to drive vehicles and use machines.

PHARMACODYNAMICS-PHARMACOKINETICS

The primary pharmacological effect of the product is the reduction of chronic venous insufficiency, diminishing stasis; the product is also effective in normalizing microvascular permeability and improving capillary resistance.
Pharmacological properties of the product have been performed in man with double blind studies, by methods to determine and quantify its activity on venous dynamics.
After oral administration in man of $^{14}$C – diosmin, it is mainly observed faecal excretion while urinary excretion represents only the 14 % of the administered dose; half-life excretion is 11 hours.
POSOLOGY, METHOD, TIME OF ADMINISTRATION

*In chronic venous disease:* 2 tablets daily (1 tablet at the main meals).

*In hemorrhoidal disease:*
- Acute crisis: 6 tablets daily for 4 days, then 4 tablets daily for 3 days.
- Chronic treatment: 2 tablets daily.

**Do not exceed the recommended doses.**

ADVERSE EFFECTS

Some cases of minor gastrointestinal and autonomic disorders have been reported, but these never required cessation of treatment.

OVERDOSE

Cases of overdose have not been reported.

SHELF LIFE AND STORAGE

The expiry date refers to the product in the intact packaging, correctly stored.

**Do not use the product after the expiry date printed on the package.**

SPECIAL WARNINGS FOR STORAGE

None.

PACKAGING AND PACKAGE

Coated tablets are packed in thermosealed blisters made from PVC/aluminium. Blisters are packed in a paper-folding box with the inside package leaflet. Box of coated tablets as applicable.