

# Venafix DS

Diosmin 900mg & Hesperidin 100mg Tablets

## COMPOSITION:

Each film coated tablet contains:

Diosmin	BP	900mg
Hesperidin		100mg

## Product Description:

Light brown coloured, oval shaped, biconvex, film-coated tablets scored on one side & plain on other sides.

## Pharmacodynamics/ Pharmacokinetics:

**Pharmacotherapeutic group: Venotonic and vascular protector.**

ATC code: C05CA53.

## Pharmacology

It is active upon the return vascular system in the following way:

- it reduces venous distensibility and stasis,
- in the microcirculation, it normalises capillary permeability and increases capillary resistance.

## Clinical pharmacology

Double blind controlled studies using methods by which the effects of the product on venous haemodynamics could be demonstrated and quantified have confirmed the above pharmacological properties in man.

Dose/effect relationship:

A statistically significant dose-effect relationship was established with respect to venous plethysmographic parameters: capacitance, distensibility and rate of emptying. The optimum dose-effect ratio was obtained with one tablet.

Venotonic activity increases venous tone: venous occlusion plethysmography with a mercury stress gauge demonstrated a decrease in the rate of emptying.

Microcirculatory activity

Double-blind controlled studies showed a statistically significant difference between placebo and the drug. In patients presenting with

signs of capillary fragility, product increases capillary resistance, as measured by angiostrerometry.

## Pharmacokinetics

In man, following oral administration of the substance containing 14C Diosmin:

- Excretion is mainly faecal; a mean of 14% of the dose administered is excreted in the urine.
- The elimination half-life is 11 hours.
- The drug is extensively metabolised as evidenced by the presence of various phenol acids in the urine.

## Indication

- Treatment of symptoms related to venolymphatic insufficiency (heavy legs, pain, early morning restless legs).
- Treatment of functional symptoms related to acute hemorrhoidal attack.

## Recommended Dosage:

- Venolymphatic insufficiency: 1 tablet daily, in the morning at breakfast.
- Acute hemorrhoidal attack: 3 tablets daily (in 3 divided doses) for the first 4 days, then 2 tablets per day (in 2 divided doses) for the next 3 days.

Paediatric population

The safety and efficacy of Diosmin 900mg and Hesperidin 100mg Tablets in children and adolescents under 18 years of age have not been established.

**Route of Administration:** Oral use

## Contraindications:

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

## Warnings and Precautions:

**Jauhkan daripada capaian kanak-kanak.**

**Keep out of reach of children.**

**Please consult your pharmacist/doctor before taking this product.**

The administration of this product for the symptomatic treatment of acute hemorrhoids does not preclude treatment for other anal conditions. If symptoms do not subside promptly, a proctological examination should be

performed and the treatment should be reviewed.

## Interactions with Other Medicaments:

No interaction studies have been performed. However and taking into consideration the huge post marketing experience on the product, no drug interaction has been reported to date.

## Statement on usage during pregnancy and lactation:

### Pregnancy:

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

Animal studies do not indicate reproductive toxicity.

As a precautionary measure, it is preferable to avoid the use during pregnancy.

### Breast-feeding:

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 breast-feeding or to discontinue/abstain taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

## Adverse Effects/ Undesirable Effects:

*The following adverse effects have been reported and are classified as a function of their frequency:*

Very common ( $\geq 1/10$ ); common ( $\geq 1/100$ ,  $< 1/10$ ); uncommon ( $\geq 1/1000$ ,  $< 1/100$ ); rare ( $\geq 1/10000$ ,  $< 1/1000$ ); very rare ( $< 1/10000$ ), and not known (cannot be estimated from the available data).

Nervous system disorders

*Rare effects:* dizziness, headaches, malaise.

Gastro-intestinal disorders

*Common effects:* diarrhoea, dyspepsia, nausea, vomiting.

*Uncommon effects:* colitis.

*Not known:* abdominal pain

Skin and subcutaneous tissue disorders

*Rare effects:* rash, pruritus, urticaria

*Not known:* isolated face, lip, eyelid oedema. Exceptionally Quincke's oedema

Reporting of side effects

If you experience any undesirable effect, consult your doctor or pharmacist. This includes any possible side effects not listed in this

leaflet.

You can also declare the undesirable effects directly via the national declaration system.

By reporting side effects, you can help provide more information on the safety of this medicine.

## Effects on Ability to Drive and Use Machine:

No specific studies on the effects of flavonoid fraction on the ability to drive and use machines have been performed. However, on the basis of the overall safety profile of flavonoid fraction, medicine has nor or negligible influence on these abilities.

## Overdose and Treatment:

### Symptoms

There is limited experience with product overdose. The most frequently reported adverse events in overdose cases were gastrointestinal events (such as diarrhoea, nausea, abdominal pain) and skin events (such as pruritus, rash).

## Management

Management of overdose should consist in treatment of clinical symptoms.

## Storage:

Store at temperatures not exceeding 30°C.

## AVAILABILITY:

Alu / PVC blister pack of 30's, 50's & 100's

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XL

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