25 mm

27.5 mm

Hemolax Film-Coated Tablet

1. Name of the medicinal product
Hemolax Film-Coated Tablet

2. Special notice and recommendation
Keep out of reach of children
Read the package insert carefully before use

3. Composition
Each film-coated tablet contains:
Micronized purified flavonoid fraction corresponding to:
Diosmin..... 450 mg
Flavonoids expressed as hesperidin..... 50 mg
Excipient q.s .....1 tablet

4. Pharmaceutical form
Film-coated tablet
Brown-yellow, oval-shaped film-coated tablet, biconvex and plain on both sides.

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

6. Administration and dosage
– *Usual Dose:* 2 tablets daily in 2 divided doses, mid-day and evening at meal times.
– *Acute hemorrhoidal attack:* 6 tablets daily (in 3 divided doses) for the first 4 days, then 4 tablets daily (in 2 divided doses) for the next 3 days.
– *Paediatric population:* The safety and efficacy of Hemolax in children and adolescents under 18 years of age have not been established.

7. Contraindications
Known hypersensitivity to any ingredient in the formula.

8. Special warnings and precautions for use
Hemorrhoidal attack: The administration of this product does not preclude treatment for other anal conditions. The treatment must be short-term. If symptoms do not subside promptly, a proctological examination should be performed and the treatment should be reviewed.

9. 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 of Hemolax during pregnancy.
Lactation
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 from Hemolax therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.
Toxicology: No special hazard for humans based on conventional studies of repeated dose toxicity, genotoxicity and toxicity to reproduction.

10. Effects on ability to drive and use machines
None known.

11. Interactions with other drugs
No interaction studies have been performed. No clinically relevant drug interaction has been reported to date from post-marketing experience on the product.

12. Adverse reactions
The adverse reactions reported consist mainly in gastro intestinal events (diarrhoea, dyspepsia, nausea, vomiting). Adverse reactions listed below are classified according to frequency and system organ class.
– *Nervous system disorders:* Rare: dizziness, headaches, malaise.
– *Gastrointestinal disorders:* Common: diarrhoea, dyspepsia, nausea, vomiting; Uncommon: colitis; Not known: abdominal pain.
– *Skin and subcutaneous tissue disorders:* Rare: rash, pruritus, urticarial; Not known: isolated face, eyelid and lip oedema. Exceptionally, Quincke's oedema.

13. Overdosage and management
Symptoms
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.

14. Pharmacodynamic properties
*Pharmacotherapeutic group: V*asoprotectives; capillary stabilizing agents; bioflavonoids.
ATC code: C05CA53
– *In pharmacology:* Hemolax exerts a dual action on the venous return system: at vein and venule level, it increases parietal tone and exerts an anti-stasis action; at the microcirculatory level, it reinforces capillary resistance and normalises capillary permeability.
– *Dose/effect relationship:* Statistically significant dose-effect relationships have been demonstrated for the following venous plethysmography parameters: capacitance, distensibility and emptying time. The best dose-effect ratio is obtained with 2 tablets.
– *Venotonic activity:* It increases venous tone: venous occlusion plethysmography with a mercury strain gauge revealed a reduction in venous emptying time.
– *Microcirculatory activity:* In patients with signs of capillary fragility, it increases capillary resistance as measured by angiosterrometry.
– *Efficacy and clinical safety:* The medicinal product has therapeutic activity in phlebology, in the treatment of chronic venous insufficiency (functional and organic) of the lower limbs.

15. Pharmacokinetic properties
In humans, following oral administration of the medicinal product with carbon 14-labelled diosmin: Excretion is essentially faecal and urinary excretion is on average of 14% of the administered quantity.
The elimination half-life is 11 hours.
The product is highly metabolised, this metabolism is revealed by the presence of different phenol acids in the urine.

16. Packaging
Blister of 10 tablets. Box of 6 blisters.

17. Storage condition, shelf-life
Do not store above 30ºC.
The expiry date of this pack is printed on the box. Do not use this pack after this date.

18. Name, address of manufacturer

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