

Conditions for approval "without a prescription, in a pharmacy" of a medicinal products containing diosmin (ATC code C05CA03) and diosmine, hesperidin (ATC code C05CA53)

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Medicinal products from the pharmacotherapeutic group of vasoprotectors, bioflavonoids containing the active substance diosmin (ATC code: C05CA03) and the combination of diosmin, hesperidin (ATC code: C05CA53) are approved with the prescription and distribution status "without a prescription, in a pharmacy", if they meet the following conditions:

Pharmaceutical form	Film-coated tablet Tablet
Route of administration	Oral use
Maximum allowed strength	1000 mg
Therapeutic indications	After previous diagnosis by a doctor, <product name> is indicated in adults for the treatment of: <ul style="list-style-type: none"> • signs and symptoms of chronic venous disease of the legs, such as pain, feeling of heaviness, leg tiredness, night cramps, oedema and trophic changes, • symptoms related to acute haemorrhoidal disease.
Target population	Adults
Recommended daily dose	<p><u>Chronic venous disease</u> The usual daily dose is 2 tablets of 500mg or 1 tablet of 1000mg.</p> <p><u>Acute haemorrhoidal disease</u> During the first 4 days of treatment, the daily dose is 6 tablets of 500 mg or 3 tablets of 1000mg. During the following 3 days, the recommended daily dose is 4 tablets of 500 mg or 2 tablets of 1000mg. The recommended daily dose for maintenance treatment is 2 tablets of 500 mg or 1 tablet of 1000mg.</p>
Duration of treatment	<p><u>Chronic venous disease</u> Treatment should continue for 8 weeks The patient should consult a doctor after 8 days if symptoms persist or worsen.</p> <p><u>Acute haemorrhoidal disease</u> For 7 day treatment, which corresponds to the duration of one acute episode of hemorrhoidal disease. The patient should consult a doctor after 3 days if symptoms persist or worsen.</p>
Maximum acceptable package size	60 tablets of 1000 mg 120 tablets of 500 mg
Distribution	Supply through pharmacies
Advertising to general public	Not allowed