

Size : 120 x 160 mm

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only



Euphorbia Prostrata Extract Tablets 100 mg



DESCRIPTION

Euphorbia prostrata extract tablet is greenish, oval shaped, biconvex, film-coated tablets. Euphorbia prostrata extract tablet is obtained from the aerial parts (dried leaves, stems, flowers and fruits) of *Euphorbia prostrata* Ait. (Euphorbiaceae). The active components identified in Euphorbia prostrata extract are flavonoids, phenolic acid and tannins.

COMPOSITION*

Each film coated tablet contains :

Euphorbia prostrata extract 100 mg

(Containing 3.15 – 8.25 mg total flavonoid calculated as apigenin-7-glucoside and 12.6-44.0 mg total phenolics calculated as gallic acid)

Colours : Indigo Carmine, Ferric Oxide (Yellow) and Titanium Dioxide.

INDICATIONS

Euphorbia prostrata extract tablet is indicated for treatment of hemorrhoids. It is also indicated for providing symptomatic relief to patients of grade 3 and 4 hemorrhoids following hemorrhoidectomy.

DOSAGE AND METHOD OF ADMINISTRATION

The Euphorbia prostrata extract tablet is recommended for oral administration only. The tablet can be taken without regard to meal.

The recommended dosage of Euphorbia prostrata extract tablet is as follows:

Treatment of hemorrhoids: One 100 mg tablet once daily for 14 days.

Post-hemorrhoidectomy setting in patients of grade 3 and 4 hemorrhoids: One 100 mg tablet twice daily for 14 days.

CONTRAINDICATIONS

- History of hypersensitivity to *Euphorbia prostrata* extract, flavonoids and/or any constituents of the formulation
- Bleeding disorders
- Pregnant or lactating women

WARNING AND PRECAUTIONS

Hepatic and renal dysfunction

Euphorbia prostrata extract tablet has not been evaluated in patients with evidence of hepatic and/or renal dysfunction. Therefore it should be avoided in such patients.

Euphorbia prostrata extract tablet have the potential to alter coagulation profile, thus they should be used with caution when co-administered with anticoagulant, and platelet anti-aggregant agent.

Efficacy and safety of Euphorbia prostrata extract tablet has not been evaluated in pediatric patients. The use of Euphorbia prostrata extract tablet should therefore be avoided in pediatric patients.

DRUG INTERACTIONS

No significant drug interactions have been reported with the use of Euphorbia prostrata extract tablet.

UNDESIRABLE EFFECTS

Euphorbia prostrata extract tablets are generally well tolerated. The reported adverse event are mild to moderate in intensity. No serious or severe adverse event has been reported so far. The reported adverse event are nausea, dyspepsia, abdominal pain, gastralgia, gastritis, diarrhea, dizziness, headache, contact dermatitis, allergic reaction, hypersensitivity and dry mouth. Besides the clinical adverse event, derangement of the prothrombin time (not associated with clinical symptoms of bleeding) and serum creatinine (not considered related to the study medication) have occasionally been reported.

OVERDOSE AND TREATMENT

No case of overdose with Euphorbia prostrata extract tablets has been reported till date. However in case of suspected overdose with Euphorbia prostrata extract tablets, general supportive care should be instituted.

CLINICAL PHARMACOLOGY

Mechanism of Action

Euphorbia prostrata extract tablet has been evaluated in non-clinical and clinical studies for its use in the treatment of haemorrhoidal disease. Flavonoids and phenolic acid have been reported to have anti-inflammatory, analgesic¹, antioxidant^{2,3}, haemostatic⁴, antithrombotic and vasoprotective actions. Tannins are known to possess astringent and haemostatic properties.⁵ Preclinical studies carried out on the extract have confirmed its wound healing and antihemorrhoidal activity.

Clinical Study

In a phase III study, the efficacy and safety of Euphorbia prostrata extract in patients of first and second degree hemorrhoids were evaluated in 120 subjects. The study medication was given for a period of 14 days once daily. The primary efficacy endpoint was cessation of bleeding after 14 days of therapy. The proportion of subjects with active bleeding was reduced by 80% (from a pretreatment proportion of 64.17% to a post-treatment proportion of 12.71%) following 14 days of therapy with Euphorbia prostrata extract tablets administered once a day. These results were statistically significant (p value <0.001) (Table 1).

Table 1: Bleeding Per Rectum

Symptom	Type	Pre treatment		Post treatment		P-Value
		n	%	n	%	
Bleeding	Yes	77	64.17	15	12.71	<0.001
	Spontaneous	3	3.90	4	26.67	
	On defecation	71	92.21	11	73.33	
	Spotting	3	3.90	-	-	

Similarly, secondary efficacy endpoints comprising of symptoms (pain, tenesmus, pruritus, and anal discharge) and the signs (congestion, swelling and exudation) associated with hemorrhoids also showed statistically significant improvement (p-value <0.05). The proportion of subjects with complete disappearance of signs and symptoms (based on overall assessment of improvement by subject) was 64% following 14 days of therapy with Euphorbia prostrata extract tablets administered once a day. The proportion of subjects with partial or complete improvement (based on overall assessment of improvement by subject) was 92% following 14 days of therapy with Euphorbia prostrata extract tablets administered once a day.⁶

In another study, the efficacy and safety of Euphorbia prostrata extract 100 mg tablets were evaluated in more than 100 patients of grade 3 and 4 hemorrhoids following hemorrhoidectomy. The study demonstrated that addition of Euphorbia prostrata extract tablet to the standard treatment is more effective in reducing post operative pain and producing an overall improvement in the disease condition in patients of grade 3 and 4 hemorrhoids following hemorrhoidectomy as compared to standard treatment alone.⁷

SHELF-LIFE

36 months from the date of manufacturing

PACKAGING INFORMATION

Blister pack of 5 x 2 x 7's tablets

STORAGE AND HANDLING INSTRUCTIONS

Store at a temperature not more than 25°C, protect from light and moisture.

The technology Euphorbia prostrata (treatment for piles) was developed by Dr. A.K Singla, Panjab University, Chandigarh and has been licensed to Panacea Biotec Ltd. The European Patent No. EP 0868914 is in the joint names of Panacea Biotec Ltd. and Panjab University, Chandigarh.

REFERENCES

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- Flavonoids: Chemistry, Biochemistry and Applications. Talyor and Francis Group. Edited By: Anderson M and Markham KR.
- An open label, non comparative, multicentre study to assess the efficacy and safety of euphorbia prostrata tablets in haemorrhoidal disease. Data on file, Panacea Biotec Limited.
- An open label, randomized, controlled, multicentre study to evaluate the efficacy and safety of euphorbia prostrata tablets in patients of grade 3 and 4 hemorrhoids following hemorrhoidectomy.

For more information and details contact :

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Product Name	Sitcom Tablets	Change Control No.: BCC086/16
Item Code	PPIS009F	Colours ■ Black
Size	120 x 160 mm	Revision No.:
Market	Domestic	