

Size : 160 x 200 mm



Euphorbia prostrata dry extract ethanolic 80 % v/v [(35-70):1] Cream 1% w/w



COMPOSITION*

Each g contains:

Euphorbia prostrata dry extract ethanolic 80 % v/v [(35-70):1] 10 mg
(containing 0.315-0.825mg total flavonoids calculated as apigenin-7-glucoside and
1.26-4.40 mg of total phenolics calculated as gallic acid)

Cream base

q.s

DOSAGE FORM

Cream

INDICATIONS

The *Euphorbia prostrata* dry extract cream is indicated for the treatment of 1° and 2° internal haemorrhoids.

DOSE AND METHOD OF ADMINISTRATION

The *Euphorbia prostrata* dry extract cream is to be applied locally at least twice daily and after each act of defecation for 14 days.

CONTRA-INDICATIONS

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

USE IN SPECIAL POPULATION

Euphorbia prostrata dry extract cream has not been evaluated in pregnant or lactating women. Therefore it should be avoided in pregnant or lactating women.

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

WARNINGS AND PRECAUTIONS

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

DRUG INTERACTIONS

No significant drug interactions have been reported with the use of *Euphorbia prostrata* dry extract cream.

UNDESIRABLE EFFECTS

Euphorbia prostrata dry extract creams has been found to be well tolerated. No serious or severe adverse events have been reported till date.

OVERDOSE

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

PHARMACODYNAMIC AND PHARMACOKINETIC PROPERTIES

Mechanism of Action :

Euphorbia prostrata dry extract 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, analgesic, antioxidant, haemostatic, antithrombotic and vasoprotective actions. Tannins are known to possess astringent and haemostatic properties. Preclinical studies carried out on the extract have confirmed its wound healing and antihemorrhoidal activity.

Clinical Study

The safety and efficacy of *Euphorbia prostrata* dry extract cream was evaluated in a clinical study carried in 122 patients of 1° and 2° internal hemorrhoids. The primary end point was cessation of per rectal bleeding at the end of 14 days of treatment. As shown in table below, the proportion of patients with active bleeding reduced by 84% from pretreatment proportion of 91.8% to 14.8% post treatment after 14 days of treatment with *Euphorbia prostrata* dry extract cream. The results were statistically significant ($p < 0.0001$). All of 112 patients who achieved cessation of per rectal bleeding did so by the 7th day of treatment.

Improvement in Per Rectal Bleeding at End of Treatment

		Pretreatment	Post Treatment	p-Value
Bleeding (N=122)	No	10 (8.2%)	104 (85.2%)	<0.0001
	Yes	112 (91.8%)	18 (14.8%)	

The results also showed that there was statistically significant ($p < 0.01$) improvement in symptoms (pain, tenesmus, pruritus, and anal discharge) and signs (congestion, swelling and exudation) associated with 1° and 2° internal hemorrhoids. There was no clinical or laboratory adverse event reported during the conduct of the trial. *Euphorbia prostrata* dry extract creams was found to be well tolerated.

SHELF-LIFE

36 months from the date of manufacturing.

PACKAGING INFORMATION

30 g tube

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.

For more information and details contact :

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PPIS012A

Product Name	Sitcom Cream	Change Control No.: BCC087/16
Item Code	PPIS012A	Colours ■ Black
Size	160 x 200 mm	Revision No.:
Market	Domestic	