

SUMMARY OF PRODUCT CHARACTERISTICS

Product Summary

1. Trade Name of the Medicinal product

Actinac

2. Qualitative and Quantitative Composition

Powder containing chloramphenicol 4.024% w/w, hydrocortisone acetate 4.024% w/w, allantoin 2.415% w/w, butoxyethyl nicotinate 2.415% w/w and precipitated sulphur 32.193 w/w.

3. Pharmaceutical Form

A pale yellow dry powder with a solvent for the preparation of a lotion for topical application.

Clinical Particulars

4.1 Therapeutic Indications

For the treatment of acne vulgaris or other acneform conditions.

4.2 Posology and Method of Administration

Adults & Children:

The lotion is applied to the affected area each night and morning for the first four days, after this, it is applied only at night and continued for three nights after the lesions have disappeared.

4.3 Contra-indications

In patients who have a known hypersensitivity to any of the ingredients.

4.4 Special Warnings and Precautions for Use

Avoid Actinac coming into contact with the eyes and mouth.

Early in the course of treatment, erythema may occur at the site of application and the patient may experience a sensation of warmth due to the vasodilator action of the nicotinate. In the unlikely event of a severe reaction, the patient is instructed to consult the doctor before further use of Actinac.

4.5 Interactions with other medicaments and other forms of Interaction

Not relevant

4.6 Pregnancy and Lactation

Systemic and topical administration to pregnant animals can cause abnormalities of foetal development. The relevance of this finding to human beings has not been established, but at present steroids should not be used extensively in pregnancy i.e, in large amounts or for prolonged periods.

4.7 Effects on Ability to Drive and Use Machines

Not relevant

4.8 Undesirable Effects

Not relevant

4.9 Overdose

Not applicable

Pharmacological Properties

5.1 Pharmacodynamic properties

Chloramphenicol is a broad spectrum antibiotic, particularly effective against propionobacterium acnes.

The additional active ingredients hydrocortisone acetate, allantoin, butoxyethyl nicotinate and precipitated sulphur suppress inflammation, dry the skin and consequently reduce the risk of scarring.

5.2 Pharmacokinetic Properties

Two studies attached have demonstrated minimal systemic absorption of chloramphenicol from Actinac

	No.	Treatment	Total Amount Chloraphenicol administered	% in urine	CC Blood
Healthy Subjects	12	Six 12 hourly applications of 0.5ml Actinac for 3 days	Face =37.5mg Back =37.5mg	0.45 % 0.08%	Generally < detection limit
		Two drops of chloramphenicol In each eye for 3 days.	Eyes=6.24mg	11.7%	> detection limit

Patients	8	Twice daily for 8 days	Face=100mg	0.97%	In 91.7% of plasma samples no chloramphenicol was detected
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5.3 Preclinical Safety Data

Not applicable

Pharmaceutical Particulars

6.1 List of Excipients

The powder contains Tragacanth, Myrj 53, Syloid 244, Purified Talc and Titanium Dioxide. The solvent contains Benzoic Acid and Purified Water.

6.2 Incompatibilities

Not relevant.

6.3 Shelf Life

36 Months unopened
21 days after reconstitution

6.4 Special precautions for storage

Store between 2° C – 8° C

6.5 Nature and Contents of Container

Each 20ml pack of Actinac contains 5g bottle of Actinac powder and one 16ml bottle of inert solvent. The two should be mixed together to produce 20ml of Lotion.

Each 25ml pack of Actinac contains 6.25g bottle of Actinac powder and one 20ml bottle of inert solvent. The two should be mixed together to produce 25ml of Lotion.

Each 40ml pack of Actinac contains twice the quantity of the 20ml pack i.e. 2x 5g bottle of Actinac powder mixed with 2x 16ml bottle of inert solvent

Each 50ml pack of Actinac contains twice the quantity of the 25ml pack.

6.6 Instruction for Use/Handling

None

Administrative data

7. Marketing Authorisation Holder

Peckforton Pharmaceuticals Ltd
Crewe hall,
Crewe,
Cheshire,
CW1 6UL

8 Marketing Authorisation number

PL 15760/0001

9 Date of First Authorisation/Renewal of Authorisation

3 June 1999

10 Date of (Partial) Revision of the Text

May 2000