

SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Econazine (econazole nitrate +triamcinolone acetonide 10+1mg/g cream)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains 10mg econazole nitrate and 1mg triamcinolone acetonide.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Cream

A smooth fine white color cream with pleasant aromatic odor.

4. CLINICAL PARTICULARS

4.1 Therapeutic indication:

Indicated for the topical treatment of inflammatory dermatoses where infected by susceptible organisms co-exist eg. inflammatory fungal infections and infective eczema.

4.2 Posology and method of administration:

Apply lightly over the affected area several times daily, for 14 days.

Method of administration: Topical

4.3 Contraindication:

None has been mentioned.

4.4 Special warnings and special precautions for use:

- 1) It should not be used on tubercular or luetic skin infection or on viral diseases (eg. herpes, vaccinia, varicella).
- 2) It should not be administered to patients who have previously exhibited hypersensitivity to Imidazole or corticosteroids.
- 3) Long-term continuous steroid therapy should be avoided since adrenal suppression can occur, particularly when infants or children are treated or when occlusive dressing is applied. Long-term therapy with corticosteroids can cause skin lesions such as atrophy, telangiectasia and striae.

4.5 Interaction with other FPPs and other forms of interaction:

None has been mentioned.

4.6 Pregnancy and lactation:

None has been mentioned.

4.7 Effects on ability to drive and use machines:

None has been mentioned.

4.8 Undesirable effects:

Transient local mild irritation at the application site and hypersensitivity.

4.9 *Overdose:*

Overdosage in humans has not been reported to date.

5. PHARMACOLOGICAL PROPERTIES

5.1 *Pharmacodynamic properties:*

- 1) Econazole Nitrate has high fungicidal and bactericidal activity.
- 2) Triamcinolone Acetonide has excellent anti-inflammatory, anti-pruritic, anti-allergic properties.

5.2 *Pharmacokinetic properties:*

- 1) Econazole nitrate is only slightly absorbed from the skin.
- 2) Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption.

5.3 *Preclinical safety data:*

No information available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

Propyl paraben

White petrolatum

Cetyl alcohol

Mineral oil

Dimethylpolysiloxane

Sorbitan monostearate

Polysorbate 60

Methyl paraben

Propylene glycol

Procys 03121

Purified water

6.2 Incompatibilities:

No information available.

6.3 Shelf life:

3 years from the date of manufacture.

6.4 Special precautions for storage:

Keep in an airtight container. Store at temperature below 30°C. Protect from light and moisture.

6.5 Nature and contents of container:

Aluminium tube of 10g and 20g.

6.6 Instructions for use and handling and disposal:

None has been mentioned.

7. Marketing authorization holder:

Y. S. P. INDUSTRIES (M) SDN. BHD.

Lot 3, 5 & 7, Jalan P/7, Section 13,

Kawasan Perindustrian Bandar Baru Bangi,

43000 Kajang, Selangor Darul Ehsan,

Malaysia.

8. MARKETING AUTHORIZATION NUMBER

07695/NMR/2019

9. DATE OF FIRST AUTHORIZATION

25 Jan 2022

10. DATE OF REVISION OF THE TEXT:

27 Jul 2023