

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ecostatin Cream 1% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Econazole nitrate 1.0% w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cream.

A smooth white to off-white aqueous cream, with a distinctly perfumed odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the topical treatment of fungal or yeast infections and certain skin infections caused by streptococci or staphylococci. These include ringworm (Tinea) infections, athlete's foot, paronychia, pityriasis versicolor, erythrasma, intertrigo, fungal nappy rash, candidal vulvitis and candidal balanitis.

4.2 Posology and method of administration

Adults and Children:

To be massaged gently into the affected and surrounding skin area morning and evening. It is particularly suitable for moist or weeping lesions.

Infants and neonates:

No special dosage recommendations.

Elderly:

No specific dosage recommendations or precautions apply.

4.3 Contraindications

Patients with a history of sensitivity to any of the components of the preparation.

4.4 Special warnings and precautions for use

This preparation is not for oral use. It should not be used in or near the eyes. When Ecostatin Cream is being used on the anogenital area, it is important to ensure the concurrent treatment of partners.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Pregnancy and lactation

There is no evidence of a teratogenic effect in animals. Systemic absorption is likely to be negligible. However, as with other agents, use should be avoided during the first trimester of pregnancy. There is no evidence of adverse effect of use during later stages.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Side effects are limited to local discomfort and irritation, manifested by erythema, burning or stinging sensations or pruritis.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Econazole nitrate is a broad spectrum antifungal agent, active against dermatophytes (*Trichophyton rubrum*, *Trichophyton mentagrophytes*; *Epidermophyton floccosum* and *Malassezia furfur*); pathogenic yeasts; *Candida albicans* and other *Candida* species. Also active against some gram-positive bacteria, e.g. Staphylococci and Streptococci.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

See 4.6, Pregnancy and lactation.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzoic acid
Butylated hydroxyanisole
Liquid paraffin
Ethoxylated oleic acid glycerides
Stearate esters of ethylene glycol and polyoxyethylene glycol
Perfume
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

Do not store above 25⁰C. Do not freeze.

6.5 Nature and contents of container

Blind end epoxy resin lined aluminium tubes packed in a carton. Tube sizes: 15g and 30g.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Bristol-Myers Squibb Pharmaceuticals Limited
Swords
Co. Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 2/24/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30 January 1978

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10 DATE OF REVISION OF THE TEXT

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