

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ecostatin Pessaries 150 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pessary contains Econazole nitrate 150 mg.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Pessary
Cream-white to yellowish opaque, oval pessary with a fat-like odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Vulvovaginal candidosis.

4.2 Posology and method of administration

Adults:

One pessary to be inserted at bedtime for three consecutive nights. Administration should be continued even if menstruation occurs, and despite the disappearance of signs and symptoms of the infection.

The pessary should be inserted high into the vagina while the patient is supine.

Although a three-day course of therapy usually suffices, it may be necessary to institute a second course of therapy.

Children and infants:

Vulvo-vaginal candidosis is not normally a problem in children, therefore there are no specific dosage recommendation.

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 is important to ensure the concurrent treatment of partners.

Avoid contact between the pessary and contraceptive diaphragms and condoms since the rubber may be damaged by the preparation.

4.5 Interaction with other medicinal products and other forms of interaction

None, except see 4.4 above.

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.

In pregnancy, extra care should be taken in using the applicator to prevent the possibility of mechanical trauma.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Side effects are limited to occasional 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 has a broad spectrum of antifungal activity. It is highly active against *Candida albicans* and other *Candida* species and is effective in controlling infections of the vagina and vulva caused by such organisms (thrush).

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

Hard vegetable fat

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

3 pessaries in plastic foil lined polyvinylchloride containers, packed in cardboard cartons, with applicator and directions for use.

The twin pack includes a 15g tube of cream.

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

The PIL will contain diagrammatical instructions for inserting the pessary.

7 MARKETING AUTHORISATION HOLDER

Bristol-Myers Squibb Pharmaceuticals Limited
Swords
County Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 2/24/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30 January 1978

Date of last renewal: 30 January 2003

10 DATE OF REVISION OF THE TEXT

January 2003