

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Clotrimazole 100 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Clotrimazole BP 100 mg

3 PHARMACEUTICAL FORM

Pessary (Vaginal Tablet)

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Candida vaginitis. Mixed vaginal infections where trichomonas is suspected or present and where systemic therapy is contra-indicated. Not recommended as the sole treatment for trichomonas infections.

4.2 Posology and method of administration

- a) Adults: One Pessary to be used nightly for six consecutive nights.
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- b) Children: Not recommended.
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- c) Elderly Patients: One Pessary to be used nightly for six consecutive nights.
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The clinical indications for this dosage regimen is candida vaginitis and mixed vaginal infections where trichomonas is suspected or present but is not an appropriate regimen for the sole treatment of trichomonas infections.

Route of Administration: Intra-vaginal.
The single pessary to be inserted at night.

4.3 Contraindications

None stated.

4.4 Special warnings and precautions for use

None stated.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

Clotrimazole has been shown to be foetotoxic in animals at high doses. The relevance of this to human usage is not established but it would be inadvisable to use Clotrimazole during pregnancy. Effects upon lactation are not known.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Occasionally patient may experience mild irritation or burning immediately after inserting the vaginal tablet. This may rarely be found to be intolerable and the patient will then discontinue treatment.

4.9 Overdose

None stated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Clotrimazole is fungistatic; may be fungicidal, depending on concentration; inhibits biosynthesis of ergosterol or other sterols, damaging the fungal cell wall membrane and altering its permeability; as a result, loss of essential intracellular elements may occur; also inhibits biosynthesis of triglycerides and phospholipids by fungi; in addition, inhibits oxidative and peroxidative enzyme activity, resulting in intracellular build up of toxic concentrations of hydrogen peroxide, which may contribute to deterioration of subcellular organelles and cellular necrosis. In *Candida Albicans*, inhibits transformation of blastospores into invasive mycelial form.

5.2 Pharmacokinetic properties

Clotrimazole is metabolised in the liver to inactive compounds and excreted in the faeces and urine. Following the administration of vaginal tablets of 100 mg a serum concentration equivalent to 0.03 microgrammes per ml has been detected.

Clotrimazole is about 98% bound to serum proteins.

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Sodium Bicarbonate
Adipic Acid
Magnesium Stearate
Stearic Acid
Polysorbate
Anhydrous Colloidal Silica
Lactose
Methanol
Povidone

6.2 Incompatibilities

None stated

6.3 Shelf life

24 months all pack sizes

6.4 Special precautions for storage

Store below 25°C in a dry place.

6.5 Nature and contents of container

Blister pack of PVC and aluminium foil together with polystyrene applicator.
Pack size: 6

6.6 Special precautions for disposal

No special instructions.

7 MARKETING AUTHORISATION HOLDER

Chelonia Healthcare Limited
11 Boumpoulinas Street,
3rd floor, 1060 Nicosia
Cyprus

8 MARKETING AUTHORISATION NUMBER(S)

PL 33414/0027

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

07/04/1987/30/06/1997

10 DATE OF REVISION OF THE TEXT

22/01/2009