

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

ALBICAN 100 mg Pessaries
Clotrimazole 100 mg Pessaries

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pessary contains clotrimazole 100 mg
For excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pessary
White pessary shaped tablets with parallel sides and rounded end, marked
CLOT100 on one side

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

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

4.2. Posology and method of administration

Adults including the elderly

One pessary to be used nightly for six consecutive nights

Children

Not recommended.

The clinical indications for this dosage regimen are 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

Known hypersensitivity to any of the ingredients in this product.

4.4. Special warning 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

Not applicable

4.8. Undesirable effects

Occasionally the 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

In the event of an accidental oral ingestion, gastric lavage should be performed as soon as possible after ingestion.

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

No relevant information additional to that contained elsewhere in the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Maize starch
Sodium bicarbonate
Adipic acid
Magnesium stearate
Stearic acid
Polysorbate 80
Colloidal anhydrous silica
Lactose monohydrate
Povidone

6.2. Incompatibilities

Not applicable

6.3. Shelf life

24 months

6.4. Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5. Nature and contents of container

Blister pack of PVC and aluminium foil together with polystyrene applicator.

Pack size: 6

6.6. Instructions for use and handling

Not applicable

7 MARKETING AUTHORISATION HOLDER

Chelonia Healthcare Limited
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8 MARKETING AUTHORISATION NUMBER(S)

PL 33414/0026

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