

## LABESTEN® CLOTRIMAZOLE Tablets

### COMPOSITION:

**Labesten®100mg vaginal tablets:** Each tablet contains Clotrimazole BP 100mg.

**Labesten®200mg vaginal tablets:** Each tablet contains Clotrimazole BP 200mg.

### PROPERTIES AND ACTIONS:

Labesten® vaginal tablets contain Clotrimazole, an imidazole antifungal agent which interferes with ergosterol synthesis and therefore alters the permeability of the cell membrane of sensitive fungi. Clotrimazole also has activity against some Gram-positive bacteria (though not clinically useful), and *Trichomonas vaginalis*.

### DOSAGE, ADMINISTRATION AND INDICATIONS:

Labesten® tablet should be inserted into the vagina, as high as possible, using the applicator provided. This is best achieved when lying back with legs bent up.

#### Adults:

One pessary should be inserted daily (preferably at night) for three consecutive days. A second treatment may be carried out if necessary.

There is no separate dosage schedule for the elderly.

Labesten® tablets need moisture in the vagina in order to dissolve completely; otherwise undissolved pieces of the pessary might crumble out of the vagina. Pieces of undissolved pessary may be noticed by women who experience vaginal dryness. To help prevent this it is important that the pessary is inserted as high as possible in to the vagina at bedtime.

Generally treatment during the menstrual period should not be performed due to the risk of the pessary being washed out by the menstrual flow. The treatment should be finished before the onset of menstruation.

Do not use tampons, intravaginal douches, spermicides or other vaginal products while using this product.

Vaginal intercourse should be avoided in case of vaginal infection and while using this product because the partner could become infected.

#### Children:

Not for use in children under 16.

#### Directions for insertion of vaginal tablets using the applicator.

1. Pull back the applicator plunger about 2.5 centimeters (1 inch). Insert the tablet into the cup at the end of the hollow tube (applicator).
2. Lie on your back with your knees drawn up. Insert the applicator into your vagina as far as it will comfortably go. Do NOT try to force it to go further.
3. BE SURE the applicator is in the correct position in your vagina BEFORE you push the plunger.

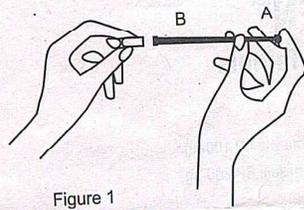


Figure 1

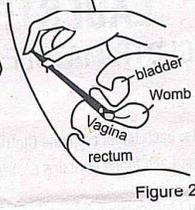


Figure 2

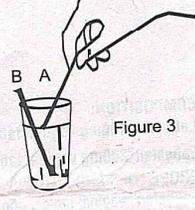


Figure 3

- 4. Then, push the plunger to place the tablet in your vagina.
- 5. Remove the applicator. Wash with mild soap and warm water. Rinse thoroughly and dry

**PRECAUTIONS, WARNING AND SIDE-EFFECTS:**

**Labesten®** vaginal tablets are contraindicated in patients with known hypersensitivity to Clotrimazole. Local reactions including irritation and burning sensation

**Labesten®** vaginal tablets should not be used for treatment in patients during the menstruation period. Pregnant women who are on medication with **Labesten®** Vaginal tablets should strictly follow the doctor's instructions.

**LEGAL CATEGORY:** Prescription only Medicine (POM).

**THERAPEUTIC CATEGORY:** ATC D01A (Gynaecological anti-infective and antiseptics – imidazole derivatives).

**STORAGE CONDITIONS:**

Store in a dry place below 30°C. Protect from light. Keep out of reach of children.

**SHELF LIFE:** As per the product label.

**PRESENTATION:**

**Labesten® 100mg vaginal tablets** presented as a Single dose packet of 6 vaginal tablets with an applicator for intravaginal insertion.

**Labesten® 200mg vaginal tablets** presented as a Single dose packet of 3 vaginal tablets with an applicator for intravaginal insertion

**LAST DATE OF REVIEW:** February 2017

**LICENSE HOLDER: LABORATORY & ALLIED LTD.**

Manufactured by:  
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