Prescribing information (Summary of Product Characteristics)

1. Name of the medicinal product.

Labesten Vaginal Tablets.

2. Qualitative and quantitative composition.

Each Tablet contains: Clotrimazole BP 100mg.
Each Tablet contains: Lactose Monohydrate BP 286.93mg.

3. Pharmaceutical form.

Pessary for vaginal administration
White, capsule shaped, biconvex tablets plain on both sides, packed in blisters of 6's and contained in a unit box with literature insert.

4 Clinical particulars.

4.1 Therapeutic indications.

Labesten vaginal tablets are indicated for the treatment of fungal and trichomonas infections of the vagina caused by or associated with pathogens sensitive to clotrimazole therapy.
They are applied in the vagina for the treatment of vulvovaginal candidiasis, trichomoniasis and any other vaginal infections caused by or associated with pathogens sensitive to clotrimazole.

4.2 Posology and method of administration.

Method of administration: Vaginal application
One vaginal tablet is inserted deep into the vagina for six consecutive nights.
The regime for treatment in pregnant patients is clotrimazole 100mg vaginal tablets for 6 consecutive nights.
Treatment should not be undertaken during the menstrual period and should be timed so as to be completed before the onset of menstruation.

4.3 Contraindications.

Hypersensitivity to clotrimazole or any of the excipients used.

4.4 Special warnings and precautions for use.

Local reactions including, irritation and burning sensation, in addition to contact allergic dermatitis may occur to some patients treated topically and in such cases the medication should be discontinued immediately.
Should not be used for treatment in patients during the menstruation period.
Pregnant women on medication with clotrimazole vaginal tablets should strictly follow the doctor's instructions.

4.5 Interaction with other medicinal products and other forms of interaction.

Concomitant medication with vaginal clotrimazole and oral tacrolimus (FK-506; immunosuppressant) might lead to increased tacrolimus plasma levels and similarly with sirolimus. Patients should thus be closely monitored for signs and symptoms of tacrolimus or sirolimus overdosage, if necessary, by determination of the respective plasma levels.
Laboratory tests have suggested that, when used together, this product may cause damage to latex contraceptives.
Consequently, the effectiveness of such contraceptives may be reduced. Patients should be advised to use alternative precautions for at least five days after using this product.

4.6. **Pregnancy and lactation.**

Fertility:
No human studies of the effects of clotrimazole on fertility have been performed, however, animal studies have not demonstrated any effects of the drug on fertility.
Pregnancy:
There is limited amount of data from the use of clotrimazole in pregnant women. Animal studies with clotrimazole have shown reproductive toxicity at high oral doses. At the low systemic exposures of clotrimazole following vaginal treatment, harmful effects with respect to reproductive toxicity are not predicted.
Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife.
During pregnancy the pessary should be inserted without using an applicator.
Lactation:
Available pharmacodynamic/toxicological data in animals have shown excretion of clotrimazole/metabolites in milk after intravenous administration. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from clotrimazole therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

4.7 Effects on ability to drive and use machines.

The medication has no or negligible influence on the ability to drive or use machinery.

4.8 Undesirable effects.
As the listed undesirable effects are based on spontaneous reports, assigning accurate frequency of occurrence for each is not possible.
Immune system disorders: Allergic reaction (syncope, hypotension, dyspnea, urticaria, pruritus).
Reproductive system and breast disorders: Genital peeling, pruritus, rash, oedema, erythema, discomfort, burning, irritation, pelvic pain, vaginal haemorrhage.
Gastrointestinal disorders: Abdominal pain.

4.9 Overdose.
No risk of acute intoxication is seen as it is unlikely to occur following a single vaginal or dermal application of an overdose (application over a large area under conditions favourable to absorption) or inadvertent oral ingestion. There is no specific antidote.
However, in the event of accidental oral ingestion, routine measures such as gastric lavage should be performed only if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). Gastric lavage should be carried out only if the airway can be protected adequately.

5. Pharmacological properties
5.1 Pharmacodynamic properties.
Pharmacotherapeutic group: Gynaecological ant-infectives and antiseptics – imidazole derivatives.
ATC code*:* G01A F02.
Mechanism of Action:
Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane.
Clotrimazole has a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeasts, moulds, etc. Under appropriate test conditions, the MIC values for these types of fungi are in the region of less than 0.062-8.0 µg/ml substrate. The mode of action of clotrimazole is fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection. In-vitro activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive.
Primarily resistant variants of sensitive fungal species are very rare; the development of secondary resistance by sensitive fungi has so far only been observed in very isolated cases under therapeutic conditions.

5.2 Pharmacokinetic properties.
Pharmacokinetic investigations after vaginal application have shown that only a small amount of clotrimazole (3 – 10% of the dose) is absorbed. Due to the rapid hepatic metabolism of absorbed clotrimazole into pharmacologically inactive metabolites the resulting peak plasma concentrations of clotrimazole after vaginal application of a 500mg dose were less than 10 ng/ml, reflecting that clotrimazole applied intravaginally does not lead to measurable systemic effects or side effects.

5.3 Preclinical safety data.
Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity and carcinogenicity. Clotrimazole was not teratogenic in reproductive toxicity studies in mice, rats and rabbits.

6. Pharmaceutical particulars.
6.1 List of excipients.
- Lactose Monohydrate
- White Corn Starch
- Sodium Starch Glycolate
- Microcrystalline Cellulose pH 101
- Povidone K-30
- Sodium Benzoate
- Sodium Bicarbonate
- Sodium Lauryl Sulphate
- Purified Talc
- Magnesium Stearate

6.2 Incompatibilities
None known.

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store in a dry place, below 30°C, Protect from light.
Keep all medicines out of reach of children.

6.5 Nature and contents of container
Packed in blisters of 6's and contained in a unit box with literature insert.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder and Manufacturing Site Addresses.
Marketing Authorization Holder:
Company Name: LABORATORY & ALLIED LTD.
Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa Road,
P.O. Box 42875 GPO 00100, Nairobi,
Country **:** Kenya.
Telephone **:** +254 20 8040306.
Telefax **:** +254 20 8040309.
E-Mail **:** info@laballied.com.

Manufacturing Site Address:
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P.O. Box 42875 GPO 00100, Nairobi,
Country : Kenya.
Telephone : +254 20 8040306.
Telefax : +254 20 8040309.
E-Mail : info@laballied.com.

8. Marketing Authorization Number:
Registration No: KENYA: **H92/102.**

9. Date of first Registration/ Renewal of the Registration:
Date of Registration: 11/08/1992.
Renewal: Retained Annually.

10. Date of revision of the text:
April 2024.

11. Dosimetry (if applicable)
Not Applicable.

12. Instructions for preparation of radiopharmaceuticals (if applicable)
Not Applicable.