1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

Summary Product Characteristics

1. **Name of the proprietary product:**
   Clotrimazole Vaginal Insert

2. **Composition :**
   Each uncoated tablets contains:
   Clotrimazole USP ……..100 mg
   Excipients q.s.

3. **Route of Administration:**

   Solid Oral

4. Clinical Particulars:

4.1 Therapeutic Indications:
The tablet is for the relief of vaginal itching, burning and discharge associated with recurrent vaginal yeast infections (vaginal candidiasis).

4.2 Posology and method of administration:

In general, a single dose treatment will be sufficient for Candida vaginitis. Unless otherwise prescribed by the doctor, the Clotrimazole Vaginal Tablet should be inserted, preferably at night into the vagina as deeply as possible (see Directions for insertion of vaginal tablets using the applicator).

This is best achieved when lying back with the legs slightly drawn up. However, the tablet may also be inserted by the doctor after the examination. If necessary a second treatment may be carried out.

If is recommended that the treatment should be timed so as to avoid the menstrual period. For prevention of re-infection the partner should be treated locally with Clotrimazole Cream at the same time.

Use during pregnancy: Clotrimazole Vaginal tablet should not be administered to pregnant women during the first trimester except on the advice of a medical practitioner.

During pregnancy the Clotrimazole Vaginal Tablet 500 mg should be inserted without using an applicator.
Directions for Insertion of vaginal tablets using the applicator.

N*ote*: Pregnant women should strictly follow the doctor's instructions.

4.3 Contraindications
It is not suitable to those who have shown hypersensitivity to clotrimazole

4.4 Special warnings and precautions for use
Not for oral use.
The drug can reduce the effectiveness of condoms, contraceptive device for women. This effect are momentary and happen at the time of the treatment.

If there is no improvement in 3 days or if symptoms have not disappeared within 7 days, then consult a medical practitioner, as not all vaginal infections are caused by yeasts.

Consult a medical practitioner if you have abdominal pain, fever or a foul-smelling vaginal discharge before or during use of this medication.

If symptoms recur within 2 months, consult a medical practitioner.

Do not use in girls under 12 years of age, except on the advice of a medical practitioner.

4.5 Interaction with other medicinal products and other forms of interaction:
Patient should concern to doctor or pharmacist if they have recently taken any other medicines obtained without prescription also inform to the doctor if they are taking tacrolimus or sirolimus (used to reduce the immune response to prevent rejection after an organ transplant.)

4.6 Pregnancy and Lactation:

During pregnancy, this tablets should not be used with the applicator. Particular attention should be paid to hygienization of the birth canal during the last 4-6 weeks of pregnancy.On physician's prescription only. Read the instructions carefully before using. For further information, consult the physician.

4.7 Effects on the ability to drive and use machines
It has no or negligible influence on the ability to drive or use machines.

4.8 Undesirable effects:

Local reactions including irritating and burning may occur.

Contact allergic-dermatitis, lower abdominal cramps, increase.

In urinary frequency or skin rash.

Hypersensitivity reactions may affect the skin (e.g. Itching, redness), breathing (shortness of breath), the circulation (e.g, a drop in blood pressure requiring treatment or even impaired consciousness) or the gastrointestinal tract (e.g. nausea, diarrhoea).

4.9 Overdose
In case of accidental oral ingestion of vaginal tablets, routine supportive measures such as gastric lavage should be performed as soon as possible.

5. Pharmacological Particulars:

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:. Antifungals , gential

ATC code: D01AC01

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 primarily 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.

In addition to its antimycotic action, clotrimazole also acts on gram-positive microorganisms (Streptococci / Staphylococci / Gardnerella vaginalis), and gram-negative microorganisms (Bacteroides).

In vitro clotrimazole inhibits the multiplication of Corynebacteria and gram-positive cocci - with the exception of Enterococci - in concentrations of 0.5-10 µg/ml substrate.

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 dermal application have shown that clotrimazole is minimally absorbed from the intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of clotrimazole were below the detection limit of 0.001 mcg/ml, suggesting that clotrimazole applied topically is unlikely to lead to measurable systemic effects or side effects.

5.3 Pre-clinical Safety:

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. In rats high oral doses were associated with maternal toxicity, embryotoxicity, reduced fetal weights and decreased pup survival.

In rats clotrimazole and/or its metabolites were secreted into milk at levels higher than in plasma by a factor of 10 to 20 at 4 hrs after administration, followed by a decline to a factor of 0.4 by 24 hrs.

6. Pharmaceutical Particulars:

List of Excipients:
Calcium Hydrogen Phosphate BP
Maize Starch BP
Povidone BP
Microcrystalline Cellulose BP
Magnesium Stearate BP
Purified Talc BP
Sodium Starch Glycollate BP

6.2 Incompatibilities:
Not applicable

6.3 Shelf Life: 36 months.

6.4 Special Precautions for storage:
Store below 25°C. Protect from light & moisture.

6.5 Nature and contents of container:
Blister pack of 1 X 6 tablets in carton along with an applicator.

6.6 Special precautions for disposal and other handling:
None.

7. APPLICANT/MANUFACTURER

LESANTO LABORATORIES
PLOT NO.9,10,11 & 20 SURVEY NO.53 MANOR ROAD,PALGHRA-401404,MAHARASHTRA INDIA .

8. Marketing Authorization Number: ---

9. Date of first Authorization /renewal of the authorization: ---

10. Date of revision of text: