1.3

Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

KLINFAST (Clindamycin & Clotrimazole Vaginal Suppositories)

2. Qualitative and quantitative composition

Each Soft Gelatin Vaginal Suppository Contains:

Clindamycin Phosphate BP

Equivalent to Clindamycin……...100 mg

Clotrimazole BP……. …..200 mg

Excipients……Q.S.

Approved colours used in capsule shell

3. Pharmaceutical form

Vaginal Suppository

Ivory Opaque coloured, Oval shaped soft gelatin vaginal suppositories.

4. Clinical particulars

4.1 Therapeutic indications

Clindamycin and Clotrimazole Suppositories are indicated in the treatment of Trichomoniasis, Candida vulvitis, Vaginal Mycoses, Vaginal Candidiasis, Bacterial Vaginitis, Infective Leucorrhoea, Mixed Vaginal Infections and Non-specific Vaginitis.

4.2 Posology and method of administration

Posology

Intravaginally: The Suppository has to be introduced deeply into the vagina in lying position.

Treatment should not coincide with the period of menstruation.

Treatment of Bacterial Vaginosis and other gynecological infection: 1 Suppository a day for 7 days before sleep.

Prophylaxis before gynecological procedures: 1 Suppository a day for 3 days before the planned gynecological procedures and 4 days after the procedures.

Method of administration:

1 suppository should be inserted as deep into the vagina as possible, for 3 consecutive nights preferably before retiring to bed.

Treatment should be timed so as to avoid the menstrual period.

Directions for use:

Wash hands thoroughly before and after insertion of Klinfast in the vagina. The suppository

should be inserted as deep into the vagina as possible. This is best achieved when lying on the back with legs pulled in a little towards body.

After insertion of Klinfast, no activity should be done such as standing, walking, running etc., hence Klinfast should be inserted while retiring to bed.

For best results take the complete therapy for 3 days. Do not discontinue in the middle.

Discontinue only if severe irritation is experienced, only after consulting the doctor.

If a particular dose is missed, administer immediately when recalled.

4.3 Contraindications

Hypersensitivity to the components of the preparation.

Clindamycin Phosphate

Clindamycin is contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin, a history of regional enteritis or ulcerative colitis, or a history of antibiotic-associated colitis.

Clotrimazole

Hypersensitivity to imidazole. First trimester of pregnancy Caution when used during pregnancy & lactation.

4.4 Special warnings and precautions for use

It is not recommended to use Clindamycin and Clotrimazole Suppository during menstruation. If in process of use of Clindamycin and Clotrimazole Suppository the apparent or long term diarrhoea occurs, the treatment should be stopped, the appropriate diagnostical procedures are to be taken, and the treatment should be prescribed, if necessary. During treatment with vaginal Suppository vaginal intercourse and use of other products with intravaginal route of introduction are not recommended.

4.5 Interaction with other medicinal products and other forms of interaction

The antagonist effect is possible between Clindamycin and erythromycin; clotrimazole, if introduced intravaginally, depresses the activity of amphotericin B and other polyene antibacterial agents. If used at the same time with nystatin the effect of clotrimazole may be suppressed. Clindamycin Phosphate and Clotrimazole Suppository contain the components which may deteriorate reliability of the latex and rubber products, such as are the condoms or contraceptive vaginal diaphragms. That’s why it is not recommended to use these products in process of treatment.

4.6 Fertility, pregnancy and lactation

There are no adequate and well controlled studies in pregnant women. Because animal

reproduction studies are not always predictive of human response, this drug should be used only if clearly indicated during the first trimester of pregnancy.

It is not known whether this drug passes into breast milk. Consult your doctor before breastfeeding.

4.7 Effects on ability to drive and use machines

None reported.

4.8 Undesirable effects

Clindamycin phosphate

Genital itching or burning; irritation not present before use of Clindamycin Suppositories; vaginal pain.

Seek medical attention right away if any of these SEVERE side effects occur:

Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); blood/mucus in stools; diarrhea; new or worsening vaginal or vulvar itching; painful sex; severe stomach cramps; white vaginal discharge.

4.9 Overdose

Symptoms of overdose may include: severe headache, tiredness, dizziness, mental/mood changes (such as irritability, depression), vision changes (such as double vision, blurred vision), dry/peeling skin, bone/joint pain, loss of appetite, yellowing skin/eyes, dark urine, severe stomach/abdominal pain.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antifungal, Antibacterial

Clindamycin Phosphate

Clindamycin works primarily by binding to the 50s ribosomal subunit of bacteria. This agent disrupts protein synthesis by interfering with the transpeptidation reaction, which thereby inhibits early chain elongation. Clindamycin and the related drug lincomycin are often discussed along with the macrolides, but are not chemically related.

Clindamycin may potentiate the opsonization and phagocytosis of bacteria even at subinhibitory concentrations. By disrupting bacterial protein synthesis, clindamycin causes changes in the cell wall surface which decreases adherence of bacteria to host cells and increases intracellular killing of organisms.

Clotrimazole

Clotrimazole is an antifungal medication commonly used in the treatment of fungal infections of both humans and animals such as vaginal yeast infections, oral thrush, and ringworm. It is also used to treat athlete's foot and jock itch.

Clotrimazole is a broad-spectrum antifungal which binds to phospholipids in the cell membrane altering cell wall permeability causing a loss in essential intracellular elements.

5.2 Pharmacokinetic properties

Clindamycin Phosphate

Absorption

~10% of topically applied drug is absorbed systemically.

No significant levels are seen in CSF, even with inflamed meninges; crosses the placenta; distributes into breast milk; high concentrations in bone and urine.

Metabolism

Hepatic

Elimination

Most of drug eliminated by hepatic metabolism

Clotrimazole

Absorption

Negligible through intact skin (topical); 3-10% (vaginal).

Metabolism

Hepatic; converted to inactive metabolites.

Excretion

Urine, faeces (as metabolites).

5.3 Preclinical safety data

Clindamycin phosphate

Transient neuromuscular blockade is a recognized side effect of clinical use of antibiotics, including clindamycin. Extensive analysis of the blockade has led to the conclusion that clindamycin exerts its main effect post-synaptically at the neuromuscular junction, with a minor component of the inhibition also occurring pre-synaptically. The basis for these effects has been determined to be the lipophilic nature of the structure of clindamycin, which allows the molecule to compete with calcium for entry into nerve terminals, resulting in interference with nerve transmission. The effect of clindamycin on neuromuscular transmission has potential relevance to gastrointestinal smooth muscle function and the development of enterocolitis. However, because systemic exposure following topical application of

clindamycin is low, it is not anticipated that patients receiving treatment with Veltin Gel will be affected.

Clotrimazole

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction and development.

The local and systemic tolerance of clotrimazole in different dosage forms was assessed in intravaginal studies in dogs and monkeys and in subacute dermal studies in rabbits. There was no evidence of treatment-related local or systemic adverse effects in any of these studies.

The oral toxicity of clotrimazole has been well-studied.

Following a single oral administration, clotrimazole was slight-to-moderately toxic in experimental animals, with LD50 values of 761 to 923 mg/kg bw for mice, 95 to 114 mg/kg bw for new born rats and 114 to 718 mg/kg bw for adult rats, > 1000 mg/kg bw for rabbits and > 2000 mg/kg bw for dogs and cats.

In repeated dose oral studies conducted in rats and dogs, the liver was found to be the primary target organ for toxicity. This was evidenced by an increase in serum transaminase activities and the appearance of liver vacuolation and fatty deposits starting at 50 mg/kg in the chronic (78-week) rat study and at 100 mg/kg in the sub chronic (13-week) dog study.

Clotrimazole has been extensively studied in in vitro and in vivo mutagencity assays, and no evidence of mutagenic potential was found. A 78-week oral dosing study of clotrimazole in rats did not show any carcinogenic effect.

6. Pharmaceutical particulars

6.1 List of excipients

Light Liquid Paraffin, White Petroleum Jelly, Gelatin, Glycerin, Methyl Paraben, Propyl Paraben, Titanium dioxide & Purified Water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 Months.

6.4 Special precautions for storage

Store in a cool, dry & dark place. Protect from light & moisture. Keep out of reach of children.

6.5 Nature and contents of container

Klinfast is Ivory Opaque coloured, Oval shaped soft gelatin vaginal suppositories, packed in printed aluminium foil and Clear PVC foil blister containing 7 Suppositories.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

M/s. GENEITH PHARM LTD.
12 Adewale Crescent, Off Ewenla Street,
Off, Oshodi, Apapa, Lagos,
Nigeria.

8. Marketing authorisation number(s)

KD/342 05/02/2022

9. Date of first authorisation/renewal of the authorisation

05/02/2022

10. Date of revision of the text

04/02/2027