

### 1.3.1 Summary of Product Characteristics (SmPC)

#### 1. Name of the medicinal product

**KLINFAST FORTE** (Clindamycin, Clotrimazole & Tinidazole 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

Tinidazole BP .....100 mg

Excipients .....Q. S.

Approved colours used in capsule shell

#### 3. Pharmaceutical form

Vaginal Suppository

Pink coloured opaque, oval shaped soft gelatin vaginal suppositories.

#### 4. Clinical particulars

##### 4.1 Therapeutic indications

Klinfast Forte is indicated in the treatment of Bacterial Vaginitis, Trichomoniasis, Vaginal Candidiasis, Candida vulvitis, Vaginal Mycoses, 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 Klifast Forte 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 Klifast Forte, no activity should be done such as standing, walking, running etc., hence Klifast Forte 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**

- Blood dyscrasias
- Decreased neutrophils
- Epileptic seizure
- First trimester of pregnancy
- Hypersensitivity

### **4.4 Special warnings and precautions for use**

It is not recommended to use Clindamycin, Clotrimazole & Tinidazole Suppository during menstruation. If in process of use of Clindamycin, Clotrimazole & Tinidazole 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 polyeneantibacterial agents. If used at the same time with nystatin the effect of clotrimazole may be suppressed. Clindamycin, Clotrimazole & Tinidazole 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**

Klifast Forte is not recommended for use in first trimester of pregnancy and should be used with caution in rest pregnancy. Consult your doctor before using it.

There is limited data on how Klinfast Forte affects breastfeeding infants. However, systemic absorption of Clindamycin, Clotrimazole & Tinidazole is negligible after topical and vaginal administration. Consult your doctor before breastfeeding.

#### 4.7 Effects on ability to drive and use machines

None reported.

#### 4.8 Undesirable effects

Very rare but the common side effects are anorexia, bitter taste, nausea, vomiting, diarrhoea, fatigue, dry mouth, abdominal distress & headache.

#### 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

Klinfast Forte comprises three medicines: Clindamycin, Clotrimazole & Tinidazole.

Clindamycin belongs to the lincomycin antibiotic group that inhibits bacterial protein synthesis, which is required for the bacteria's survival. Tinidazole is an antibiotic or antiprotozoal which kills amoeba and parasites. On the other hand, Clotrimazole belongs to the imidazole antifungal group that kills fungi by causing holes in their cell membrane, thereby leaking all content.

#### 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).

### Tinidazole

#### Absorption

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

#### Metabolism

Hepatic, mainly via CYP3A4. Partly metabolized by oxidation, hydroxylation and conjugation.

#### Excretion

20-25% of unchanged drug is excreted in urine and 12% is excreted via feces.

## **5.3 Preclinical safety data**

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.

## **6. Pharmaceutical particulars**

### **6.1 List of excipients**

Light Liquid Paraffin, White Petroleum Jelly, Gelatin, Glycerin, Methyl Paraben, Propyl Paraben, Ponceau 4R, 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 place below 30°C. Protect from light. Keep all medicines out of reach of children.

### **6.5 Nature and contents of container**

Klinfast Forte is pink coloured opaque, oval shaped soft gelatin vaginal suppositories, packed

**Module 1- Administrative & Prescribing Information**  
**Product Name: KLINFAST FORTE**  
**(Clindamycin, Clotrimazole & Tinidazole Vaginal Suppositories)**

**Dosage Form & Label Claim: Vaginal Suppository**  
**Each Soft Gelatin Vaginal Suppository Contains:**  
**Clindamycin Phosphate BP Eq. to Clindamycin 100 mg**  
**Clotrimazole BP 200 mg**  
**Tinidazole BP 100 mg**  
**Excipients Q.S.**  
**Approved colours used in capsule shell**

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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