#### Information For the User

# Clindamycin (100mg) + Clotrimazole (200mg)

# **Clinzadin C softgel**

Clindamycin (100mg) + Clotrimazole (200mg) Soft Gel

#### **Composition**

#### **Each soft gel contains:**

- Clindamycin (as Clindamycin Phosphate) 100 mg
- Clotrimazole 200 mg

### **Excipients:**

Gelatin, glycerin, and other suitable excipients.

#### **Description**

Clindamycin is a lincosamide antibiotic that works by inhibiting bacterial protein synthesis, while Clotrimazole is an antifungal agent that disrupts the fungal cell membrane. This combination is designed to treat infections caused by a range of bacterial and fungal pathogens.

#### **Indications**

This combination is indicated for the treatment of:

- Vaginal infections caused by mixed bacterial and fungal infections, including:
  - Bacterial vaginosis (due to Gardnerella vaginalis and other susceptible organisms)
  - Candidiasis (due to Candida species)

It is used for infections where both bacterial and fungal pathogens are involved, particularly when a mixed infection has been diagnosed.

# **Dosage and Administration**

#### · Adults:

- o The usual dose is 1 soft gel daily, typically for 7-14 days, depending on the severity of the infection. The soft gel should be taken orally with a full glass of water, either with or without food.
- Pediatric patients:
  - Not recommended for use in children unless prescribed by a healthcare provider.
- Renal and Hepatic Impairment:

   No

   specific dosage adjustments are generally required for renal or hepatic impairment.

   However, this combination should be used with caution in patients with significant liver dysfunction.

#### **Mechanism of Action**

- Clindamycin: Inhibits bacterial protein synthesis by binding to the 50S ribosomal subunit of susceptible bacteria, thereby preventing their growth and replication. It is effective against a wide range of Grampositive cocci and some anaerobic bacteria.
- Clotrimazole: Interferes with the synthesis of ergosterol, a key component of the fungal cell membrane, leading to cell membrane disruption and eventual cell death. It is particularly effective against Candida species and other common fungal pathogens.

#### **Contraindications**

- Hypersensitivity to clindamycin, clotrimazole, or any of the components of the formulation.
- History of allergic reactions to other antifungal or antibiotic agents in the same class.

# **Warnings and Precautions**

- Gastrointestinal side effects: Clindamycin can cause diarrhea, and in rare cases, may lead to Clostridium difficile-associated diarrhea (CDAD), which can be lifethreatening. If diarrhea occurs, discontinue use immediately.
- Liver Function: Use with caution in patients with hepatic impairment, as both drugs are metabolized in the liver. Liver function tests should be monitored in long-term use.
- Fungal Resistance: Overuse of Clotrimazole may lead to the development of fungal resistance. This combination should be used only when a mixed infection (both bacterial and fungal) is diagnosed.
- Pregnancy: This combination should be used during pregnancy only if clearly needed.
   Clindamycin is classified as a Category B drug, and Clotrimazole as Category C.
   Consult a healthcare provider before use during pregnancy.
- Breastfeeding: Clindamycin is excreted in breast milk, and while generally considered safe for use during lactation, consult your healthcare provider if you are breastfeeding. Clotrimazole may also pass into breast milk but is generally considered safe for breastfeeding mothers.

#### Side Effects

#### **Common Side Effects:**

- Gastrointestinal: nausea, vomiting, abdominal pain, diarrhea
- · Skin: rash, itching
- Headache, dizziness
- Vaginal irritation (if used for vaginal infections)

#### **Serious Side Effects:**

- Clostridium difficile-associated diarrhea (CDAD)
- Severe allergic reactions: anaphylaxis, angioedema, difficulty breathing
- Liver toxicity: jaundice, elevated liver enzymes
- Severe skin reactions: Stevens-Johnson syndrome, erythema multiforme

# **Drug Interactions**

- Erythromycin: May reduce the effectiveness of clindamycin, and should be avoided if possible.
- Cyclosporine: Clindamycin may increase the serum levels of cyclosporine, raising the risk of toxicity.
- Other antifungals: Combining with other antifungal agents may enhance the risk of hepatic toxicity or other side effects.

#### **Storage**

- Store at 15°C to 25°C (59°F to 77°F).
- Keep in a cool, dry place, protected from light.
- · Do not freeze.
- Keep out of reach of children.

Note: Always consult with a healthcare provider before using this medication to ensure it is appropriate for your condition. If you experience any unusual side effects or symptoms, seek medical attention immediately.

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