

**Summary of Product
Characteristics VAGID-CL**

1. NAME OF THE MEDICINAL

PRODUCT: VAGID-CL

2. QUANTITATIVE AND QUANTITATIVE COMPOSITION:

Each vaginal suppository contains:

Clindamycin Phosphate USP equivalent Clindamycin

100 mg Clotrimazole BP 200

mg

Excipient(s) with known effect;

Macrogols (Polyethylene Glycol)

1500.....1652.441mg

Macrogols (Polyethylene Glycol) 6000.....20.000mg

List of excipients is enclosed in section 6.1.

3. PHARMACEUTICAL FORM: Suppositories

4. CLINICAL PARTICULARS:

4.1 Therapeutic Indications:

VAGID-CL is indicated for the treatment of infective leucorrhoea, vaginal candidiasis, bacterial vaginitis, trichomoniasis, mixed infections and non-specific vaginitis.

4.2 Posology and method of administration:

One vaginal suppository to be used every night for 3 consecutive nights.

4.3 Contraindications:

VAGID-CL vaginal suppository is contraindicated in patients hypersensitive to clindamycin, lincomycin, clotrimazole or any other excipient of the formulation and in patients with known history of regional enteritis, ulcerative colitis or antibiotic associated colitis.

4.4 Special warnings and precautions:

For vaginal use only. Not to be taken orally.

After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated mild cases of pseudomembranous colitis usually respond to discontinuation of drug alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective

against clostridium difficile colitis.

The use of clindamycin vaginal suppository may result in the overgrowth of non-susceptible organism the vagina. In clinical studies using clindamycin vaginal suppository, treatment related moniliasis was reported in 2.7 % and vaginitis in 3.6% of 589 non pregnant women. Moniliasis, as reported here, includes the terms: vaginal or non vaginal moniliasis and fungal infection vaginitis includes the terms: vulvovaginal disorder, vaginal discharge and vaginitis/ vaginal infection.

The patient should be instructed not to engage in vaginal intercourse or use other vaginal products (such as tampons or douches) during treatment with this product. The patient should be advised that these suppositories use an oleaginous base that may weaken latex or rubber products such as condoms or vaginal contraceptive diaphragms. Therefore, the use of The patient should be advised that these suppositories use an oleaginous base that may weaken latex or rubber products such as condoms or vaginal contraceptive diaphragms. Therefore, the use of such products within 72 hours following treatment with clindamycin vaginal suppository is not recommended.

Medical advice should be sought before using clotrimazole if this is the first time the patient has experienced symptoms of candidal vaginitis. Caution is advised in patients with previous history of sexually transmitted disease or exposure to partner with sexually transmitted disease, patients over 60 years of age, known hypersensitivity to imidazoles or other vaginal antifungal products. Vaginal clotrimazole should not be used if the patient has any of these symptoms: irregular vaginal bleeding or blood – stained discharge, vulval or vaginal ulcers blisters or sores, lower abdominal pain or dysuria, any adverse such as redness, irritation or swelling associated with the treatment, fever or chills nausea or vomiting, diarrhoea, foul smelling vaginal discharge.

4.5 Interactions with other medicinal products and other forms of interaction:

Clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. Therefore, it should be used with caution in patients receiving such agents.

Laboratory tests have suggested that when used together, clotrimazole 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 clotrimazole.

4.6 Pregnancy and lactation:

VAGID-CL should be used during pregnancy only if the potential benefit justifies the potential risk of fetus.

Clindamycin has been detected in human milk after oral or parenteral administration it is not known if clindamycin is excreted in human milk following the use of vaginally administered clindamycin phosphate. Because of potential for serious adverse reactions in nursing infants from clindamycin phosphate, a decision should be made whether to discontinue nursing or to discontinue the drug, taking in to account the importance of the drug to the mother. Excretion of clotrimazole in breast milk is unknown. Therefore, VAGID-CL suppository should be used in lactating women only of clearly needed.

4.7 Effects on ability to drive and use machines:

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects:

Clindamycin: Adverse events reported by 1 % or more of patients associated with the use of clindamycin vaginal suppositories were vulvovaginal disorder, vaginal pain, vaginal monilliasis and fungal infection.

Other adverse events reported by < 1 % of patients include menstrual disorder, dysuria, pyelonephritis, vaginal discharge, vaginitis / vaginal infection, abdominal cramps, localized abdominal pain, fever, flank pain, generalized pain, headache, localized edema, monilliasis, diarrhoea, constipation, nausea, vomiting, non-application site pruritis, rash, application site pain and application site pruritis, exanthema.

Clotrimazole: Rarely patients may experience local mild burning or irritation immediately after inserting the suppository. Very rarely the patient may find this intolerable and stop the treatment. Other adverse effects associated with the use of clotrimazole were allergic reaction (syncope, hypertension, dyspnoea, and gastrointestinal disorders), pain, pruritis and rash.

‘Reporting of suspected adverse reactions:

Healthcare professionals are requested to report any suspected adverse reactions to the National Regulatory Agents

4.9 Overdose:

Information regarding overdoses with VAGID-CL is not available. Information regarding overdose and the possible treatment if it occurs, with the individual components is given below:

Clindamycin: Vaginally applied clindamycin phosphate could be absorbed in sufficient amounts to produce systemic effects.

Clotrimazole: 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). It should be carried out only if the airway can be protected adequately.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

Clindamycin interferes with bacterial protein synthesis, by binding to the 50S subunit of the bacterial ribosome. This causes antagonism if administered simultaneously and possible cross-resistance. Although Clindamycin Phosphate is inactive in vitro, rapid in vivo hydrolysis converts this compound to the antibacterially active clindamycin. Clindamycin is an antimicrobial agent active invitro against most strains of the following organisms that have been reported to be associated with bactreial vaginosis such as Gardnerella vaginalis; Mobiluncus spp; Bacteroids spp; Mycoplasma hominis; Peptostreptococcus spp.

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of cytoplasmic membrane. Clotrimazole has a broad spectrum of action in vivo and in vitro, which includes dermatophytes, yeast moulds, etc. 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.

5.2 Pharmacokinetic properties:

Absorption of clotrimazole after vaginal application was estimated to be between 3 and 10%. Fungicidal concentrations of clotrimazole in plasma were lower than 0.01 micrograms/ml, demonstrating that clotrimazole is rapidly metabolized. Following intravaginal administration of the clindamycin phosphate, systemic absorption averaged 30%. Systemic exposure to clindamycin from the ovule is considerably lower than from a therapeutic oral dose.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients:

Polyethylene-Glycol 1500 BP, Polyethylene-Glycol 6000, Methyl paraben BP, Propyl Paraben BP, Butylated Hydroxytoluene BP.

6.2 Incompatibilities:

Not applicable

6.3 Shelf Life:

2 years

6.4 Special precautions for storage:

Keep in a dry place, below 30°C. Protect from light. Keep out of reach of children.

6.5 Nature and contents of container:

VAGID-CL is available in strip of 3 Vaginal Suppositories packed in a carton along with leaflet.

6.6 Special precautions for disposal and

other handling: No special requirements

7. MARKETING AUTHORISATION HOLDER:

Bliss GVS Pharma
Ltd. 102, Hyde Park,
Saki Vihar Road,
Andheri (East),
Mumbai - 400 072.

8. MARKETING AUTHORIZATION NUMBER

H2015/CTD771/033

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

