Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:
Klovinal pessary

2. Qualitative and quantitative composition
Each vaginal pessary contains Metronidazole BP 500mg; Clotrimazole BP 100mg; Lactobacillus spores 150 million spores.
Excipoent with known effect Prolyethylene Glycol 1500.
For excipients see section 6.1

3. Pharmaceutical form
Vaginal Pessary White to off white bullet shaped pessaries.

4. Clinical particulars

4.1 Therapeutic indications
KLOVINAL pessary is indicated for vaginal infection like Trichomoniasis, bacterial vaginosis, and Vulvo – vaginal candidiasis.

4.2 Posology and method of administration
One KLOVINAL vaginal pessary to be inserted preferably at bed time for 6 consecutive nights.

4.3 Contraindications
KLOVINAL is contraindicated in women with hypersensitivity and/or allergy to any components of the product.

4.4 Special warnings and precautions for use

Precautions:
Discontinue the treatment if irritation and/or sensitivity occurred
Avoid usage in first trimester of pregnancy
Previous history of sexually transmitted disease or exposure to partner with sexually transmitted disease
Aged under 16 or over 60 years
Known hypersensitivity to imidazoles or other vaginal antifungal products
Not to be taken orally.
Keep medicine out of reach of children

Warnings
Irregular vaginal bleeding

Abnormal vaginal bleeding or a blood-stained discharge

Vulval or vaginal ulcers, blisters or sores

Lower abdominal pain or dysuria

Any adverse events such as redness, irritation or swelling associated with the treatment

Fever or chills

Nausea or vomiting

4.5 Interaction with other medicinal products and other forms of interaction

Inhibits metabolism of warfarin and potentiates the anticoagulant effect

Causes an intolerance to alcohol similar to disulfiram (therefore, avoid alcohol for 24 hours after administration) abdominal cramps, nausea, vomiting, headaches and flushing occur when co-ingested with alcohol

Cimetidine prolongs the plasma clearance by inhibiting metabolic enzymes; conversely,drugs that induce liver enzymes (e.g. Phenobarbital) may increase the elimination of metronidazole

May impair barrier contraceptives

Concomitant medication with vaginal Clotrimazole and oral tacrolimus might lead to increased tacrolimus plasma levels. Patients should thus be closely monitored for signs and symptoms of tacrolimus overdosage, if necessary, by determination of the respective plasma levels

Laboratory tests have suggested that, when used together, this product may cause damage to latex contraceptives.

4.6 Pregnancy and Lactation

Metronidazole crosses the placental barrier and it effects human fetal organogenesis therefore its use in pregnancy should be carefully evaluated.

Metronidazole is excreted in human milk hence unnecessary exposure to the drug should be avoided.

Klovinal should be used during pregnancy and lactation only if the benefits outweigh the risks.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Digestive upsets: Abdominal cramps, nausea, vomiting, diarrhea, oral mucositis, taste disorders, loss of appetite, exceptional and reversible cases of pancreatitis.

Allergic reactions: Rash, pruritus, flushing, urticaria, fever and angioedema, exceptional anaphylactic shocks and very rare pustular eruptions.

Peripheral and central nervous system disorder: Peripheral sensory neuropathy, headache, dizziness, convulsions and ataxia.

Psychiatric disorders: Psychotic disorders including confusion and hallucinations.

Visions disorders: Transient vision disorders such as diplopia or myopia may occur.
Hematology disorders: Very rare cases of agranulocytosis, neutropenia and thrombocytopenia.
Liver: very rare cases of reversible abnormal liver function tests and cholestatic hepatitis have been reported.

4.9 Overdose
Data not available

5. Pharmacological properties
5.1 Pharmacodynamic properties
Metronidazole has antiprotozoal and antibacterial actions and is effective against Trichomonas vaginalis and other protozoa including Entamoeba histolytica and Giardia lamblia and against anaerobic bacteria.
Clotrimazole has a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeasts, 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.
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
Vaginal administration of Metronidazole corresponds to the local action, where the concentration of the drug at the site of action is very high comparative to that of in the serum.
Pharmacokinetic investigations after vaginal application have shown that only a small amount of Clotrimazole (3 – 10% of the dose) is absorbed. Due to the rapid hepatic metabolism of absorbed Clotrimazole into pharmacologically inactive metabolites the resulting peak plasma concentrations of Clotrimazole after vaginal application of a 500mg
dose were less than 10 mcg/ml, reflecting that Clotrimazole applied intravaginally does not lead to measurable systemic effects or side effects.

5.3 Preclinical safety data
Metronidazole has been shown to be carcinogenic in the mouse and in the rat following chronic oral administration however similar studies in the hamster have given negative results. Epidemiological studies have provided no clear evidence of an increased carcinogenic risk in humans.
Metronidazole has been shown to be mutagenic in bacteria in vitro. In studies conducted in mammalian cells in vitro as well as in rodent or humans in vivo, there was inadequate evidence of a mutagenic effect of metronidazole, with some studies reporting mutagenic effects, while other studies were negative.

There are no pre-clinical data of relevance for clotrimazole, which are additional to the information included in other sections of the SmPC.

6. Pharmaceutical Particulars

6.1 List of Excipients

Polyethylene Glycol 1500
Methyl paraben
Propyl paraben
Butylated Hydroxytoluene

6.2 Incompatibilities

Not known

6.3 Shelf-Life

24 months

6.4 Special Precautions for storage

6.5 Nature and Content of container

6.6 Special precautions for disposal and other handling

7. Marketing Authorization Holder

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

8. Marketing Authorization Number

9. Date of first authorization/renewal of the authorization

31/7/2024

10. Date of revision of the text

13/5/2025