

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

SYSCAN-CL

(Clindamycin and Clotrimazole Soft Gelatin Capsules for Vaginal Use)

COMPOSITION

Each soft gelatin capsule for vaginal use contains:

Clindamycin Phosphate B.P. equivalent to Clindamycin 100 mg

Clotrimazole I.P. 200 mg

Excipients q.s.

Approved colors used in capsule shell.

PROPERTIES

Clotrimazole is an imidazole and has broad-spectrum anti-fungal action. It brings about its therapeutic effect by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis alters the permeability of the cell membrane of sensitive fungi and leads to structural and functional impairment of the cytoplasmic membrane. It has fungicidal action against *Candida albicans*, other species of *Candida* and also trichomonocidal action.

Clindamycin is a lincosamide antibiotic primarily acting against Gram positive and a wide range of anaerobic bacteria. It is congener of lincomycin. Clindamycin inhibits bacterial protein synthesis by its action at the bacterial ribosome. The antibiotic binds preferentially to the 50S ribosomal subunit and affects the process of protein synthesis. Clindamycin has antimicrobial activity against *Bacteroides* spp., *Gardnerella vaginalis*, *Mobiluncus* spp., *Mycoplasma hominis*, *Pepto-streptococcus* spp., *Haemophilus* spp. and *Corynebacterium*.

INDICATIONS

Trichomoniasis, *Candida* vulvitis, Vaginal mycoses. Vaginal Candidiasis, Bacterial Vaginitis. Infective Leucorrhoea, Mixed Vaginal Infections and nonspecific vaginitis.

CONTRAINDICATIONS

Syscan-CL is contraindicated in women with a history of hypersensitivity to Clotrimazole (or azole group) and Clindamycin (or lincomycin group). Syscan-CL is also contraindicated in women with a history of regional enteritis, ulcerative colitis or 'antibiotic associated' colitis (pseudomembranous colitis).

WARNINGS AND PRECAUTIONS

The patient should be instructed not to engage in vaginal intercourse or use of other vaginal products (such as tampons or douches) during treatment with clindamycin.

If there is a lack of response to Syscan-CL, appropriate microbiological studies should be repeated to confirm the diagnosis and rule out other pathogens before instituting another course of therapy. Clindamycin is found in very low levels in the serum (< 5%) following multiple topical applications. No systemic accumulation is seen. Intravaginal administration of

Clotrimazole in human has negligible systemic absorption (3-10%). Thus with Syscan-CL negligible systemic effects are anticipated. Syscan-CL is to be administered intravaginally and is not to be taken orally.

Pregnancy:

Teratogenic effects

Pregnancy Category B

In clinical trials with pregnant women, the systemic administration of clindamycin during the second and third trimesters has not been associated with an increased frequency of congenital abnormalities. There are no adequate studies in pregnant women during the first trimester of pregnancy. Clindamycin should be used during the first trimester of pregnancy only if clearly needed.

PREGNANCY AND LACTATION

Experimental and clinical investigations gives to indication of harmful effects to the mother or child when clotrimazole is used during pregnancy. However, there are no adequate and well-controlled studies of use of Clindamycin in pregnant women. Hence Syscan-CL should be used during pregnancy only if it is a must (under the advice of Physician) Syscan-CL may be used in lactation with caution.

ADVERSE EFFECTS

Syscan-CL soft gelatin capsule for vaginal use are well tolerated locally i.e. intravaginally. In isolated cases, vaginal irritation, itching, burning, dyspareunia and in rare cases, slight increase in urinary frequency and burning or irritation in the sexual partner have been observed. Very rarely the patient may find this irritation intolerable and in Hypersensitivity reactions may occur.

IMPORTANT

Only for vaginal insertion.

Not for oral use.

Pregnant, lactating women should strictly abide by the instructions of their Physicians.

PRESENTATION OF SALES PACK

Pack of 3 soft gelatin capsules for vaginal use.

APPLICATION AND DOSAGE

1 soft gelatin capsule should be inserted into the vagina, for 3 consecutive nights preferably before retiring to bed. Treatment should be timed so as to avoid the menstrual period.

DIRECTIONS FOR USE

1. Wash hands thoroughly before and after insertion of Syscan-CL in the vagina.
2. The soft gelatin capsule 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 the body.

3. After insertion of Syscan-CL, no activity should be done such as standing, walking running etc.hence Syscan-CL should be inserted while retiring to bed.
4. For best results take the complete therapy for 3 days. Do not discontinue in the middle.
5. Discontinue only if severe irritation is experienced, only after consulting the doctor.
6. If a particular dose is missed, administer immediately when recalled.

STORAGE

Store in a dry place at a temperature not exceeding 25°C, Protected from light. Keep out of reach of children.

PRESENTATION

Syscan-CL is available as 3 soft-gelatin capsule for vaginal use.

MARKETED BY



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