SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM:

DALACIN® VC Vaginal cream

COMPOSITION:

DALACIN VC contains the following per gram:

Clindamycin phosphate equivalent to clindamycin base: 20 mg

Benzyl alcohol (preservative): 1 % m/m

Excipients:

Cetostearyl alcohol, mineral oil (viscosity 180), mixed fatty acid esters (cutina CP), polysorbate 60 (food grade), propylene glycol, sorbitan monostearate and stearic acid

CATEGORY AND CLASS:

A 20.1.1 Broad and medium spectrum antibiotics

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Although clindamycin phosphate is inactive *in vitro*, rapid *in vivo* hydrolysis converts this compound to the antibacterially active clindamycin.

Culture and sensitivity testing of bacteria are not routinely performed to establish the diagnosis of bacterial vaginosis. Standard methodology for the susceptibility testing of the potential bacterial vaginosis pathogens, *Gardnerella* vaginalis, *Mobiluncus* spp., or Mycoplasma *hominis*, has not been defined.

Clindamycin inhibits bacterial protein synthesis at the level of the bacterial ribosome. The antibiotic binds preferentially to the 50S ribosomal subunit and affects the process of peptide chain initiation.

Antagonism has been demonstrated between clindamycin and erythromycin *in vitro*. The clinical significance of this interaction is unknown.

Cross-resistance between clindamycin and lincomycin has been demonstrated.

Pharmacokinetic properties:

Following a once a day intravaginal dose of 100 mg of clindamycin phosphate vaginal cream 2 %, administered to 6 healthy female volunteers for 7 days, approximately 4 % (range 0,6 % to 11 %) of the administered dose was absorbed systemically. The peak serum clindamycin concentration observed on the first day averaged 18 ng/ml (range 4 to 47 ng/ml) and on day 7 it averaged 25 ng/ml (range 6 to 61 ng/ml). These peak concentrations were attained approximately 10 hours post-dosing (range 4 – 24 hours).

Following a once a day intravaginal dose of 100 mg of clindamycin phosphate vaginal cream 2 %, administered for 7 consecutive days to 5 women with bacterial vaginosis, absorption was slower and less variable than that observed in healthy females. Approximately 4 % (range 2 % to 8 %) of the dose was absorbed systemically. The peak serum clindamycin concentration observed on the first day averaged 13 ng/ml (range 6 to 34 ng/ml) and on day 7 it averaged 16 ng/ml (range 7 to 26 ng/ml). These peak concentrations were attained approximately 14 hours post-dosing (range 4 – 24 hours).

There was little or no systemic accumulation of clindamycin after repeated vaginal dosing of clindamycin phosphate vaginal cream 2 %. The systemic half-life was 1,5 to 2,6 hours.

Geriatric use:

Clinical studies for clindamycin phosphate vaginal cream 2 % did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

INDICATIONS:

DALACIN VC is indicated in the treatment of symptomatic bacterial vaginosis in non- pregnant women.

Other pathogens commonly associated with vulvovaginitis e.g. *Trichomonas vaginalis, Candida albicans, Chlamydia trachomatis, Neisseria gonorrhoeae and Herpes simplex* virus should be ruled out by appropriate methods.

CONTRAINDICATIONS:

DALACIN VC is contraindicated:

- in patients with a history of hypersensitivity to clindamycin, lincomycin or any of the components of these products.
- in individuals with a history of antibiotic-associated colitis, ulcerative colitis, or regional colitis (Crohn's disease).
- Pregnancy and lactation (see HUMAN REPRODUCTION)

WARNINGS AND SPECIAL PRECAUTIONS:

The use of DALACIN VC may result in the overgrowth of non-susceptible organisms particularly yeasts (like *Candida albicans*).

Clindamycin has been associated with diarrhoea and in some cases pseudomembranous colitis. Minimal absorption (approximately 4 %) occurs following the use of DALACIN VC intravaginally; however, if significant or prolonged diarrhoea occurs DALACIN VC should be discontinued and appropriate diagnostic procedures and treatment provided as necessary.

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

DALACIN VC contains mineral oil that may weaken latex or rubber products, such as condoms or vaginal contraceptive diaphragms. The use of such products within 72 hours following treatment with DALACIN VC is not recommended.

Use in children;

Safety and efficacy in paediatric patients have not been established.

Effects on ability to drive and use machines:

The effect of DALACIN VC on the ability to drive or operate machinery has not been evaluated.

INTERACTIONS:

Systemic clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of neuromuscular blocking medicines. Therefore, neuromuscular blocking medicines should be used with caution in patients on treatment with DALACIN VC.

HUMAN REPRODUCTION:

Pregnancy:

Safety in pregnancy has not been established (see CONTRAINDICATIONS).

DALACIN VC should not be used during pregnancy.

Lactation:

It is not known if DALACIN VC is excreted in breast milk following the use of vaginally administered

DALACIN VC.

Orally and parenterally administered DALACIN VC has been reported to appear in breast milk. Therefore, mothers on treatment with DALACIN VC should not breastfeed their infants.

DOSAGE AND DIRECTIONS FOR USE:

Dosage:

The recommended dose is one applicator full (approximately 5 grams, which contains approximately 100 mg of clindamycin phosphate) of cream intravaginally, preferably at bedtime, for 3 to 7 consecutive days.

Concomitant use with other intravaginal products is not recommended.

Directions for use:

1. Plastic disposable applicators are provided with this package. They are designed to allow proper vaginal administration of the cream.
2. Remove cap from cream tube. Screw a plastic applicator on the threaded end of the tube.
3. Rolling tube from the bottom, squeeze gently and force the medication into the applicator. The applicator is filled when the plunger reaches its pre-determined stopping point.
4. Unscrew the applicator from the tube and replace the cap.
5. While lying on your back, firmly grasp the applicator barrel and insert into vagina as far as possible without causing discomfort.
6. Slowly push the plunger until it stops.
7. Carefully withdraw applicator from the vagina, and discard applicator.

SIDE EFFECTS:

The safety of DALACIN VC was evaluated in both non-pregnant patients and patients during their

second and third trimesters of pregnancy.

Side effects are categorised as follows:

Very common (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1 000, < 1/100); rare (≥ 1/10 000, < 1/1 000); very rare (< 1/10 000), including isolated reports

System organ class	**Frequency**	**Side effect**
Infections and infestations	Common	Fungal infections, candida infections
	Uncommon	Bacterial infection
	Not known	Skin candida
Immune system disorders	Uncommon	Hypersensitivity
Endocrine disorders	Not known	Hyperthyroidism
Nervous system disorders	Common	Headache, dizziness, dysgeusia
Ear and labyrinth disorders	Uncommon	Vertigo
Respiratory, thoracic and mediastinal disorders	Common	Upper respiratory infection
	Uncommon	Epistaxis
Gastrointestinal disorders	Common	Abdominal pain, constipation, diarrhoea, nausea, vomiting
	Uncommon	Abdominal distension, flatulence, breath odour
	Not known	Gastrointestinal disorder, dyspepsia
Skin and subcutaneous tissue disorders	Common	Pruritus (non-applicable site), rash
	Uncommon	Urticaria, erythema
	Not known	Maculopapular rash
Musculoskeletal and connective tissue disorders	Common	Back pain
Renal and urinary disorders	Common	Urinary tract infection, glycosuria,

		proteinuria
	Uncommon	Dysuria
Pregnancy, puerperium and perinatal conditions	Common	Abnormal labour
Reproductive system and breast disorders	Very common	Vulvovaginal candidiasis
	Common	Vulvovaginitis, vulvovaginal disorder, menstrual disorder, vulvovaginal pain, metorrhagia, vaginal discharge
	Uncommon	Trichomonal vulvovaginitis, vaginal infection, pelvic pain
	Not known	Endometriosis
General disorders and administration site conditions	Not known	Inflammation, pain
Investigations	Uncommon	Microbiology test abnormal. Abnormal microbiologic test findings on examination of body fluids, substances and/or tissues which typically mean positive culture findings in specimens from organs, systems and/or tissues

Post-marketing:

The following post-marketing adverse event has been reported with DALACIN VC:

Gastrointestinal disorders: Pseudomembranous colitis

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Vaginally applied clindamycin phosphate contained in DALACIN VC can be absorbed in sufficient amounts to produce systemic effects. Accidental ingestion of the product could be accompanied by

effects related to therapeutic levels of oral clindamycin. In the event of overdosage treatment should be symptomatic and supportive.

IDENTIFICATION:

A white, semi-solid cream.

PRESENTATION:

Cream containing 2 % clindamycin base (as the phosphate), intended for intravaginal use. DALACIN VC is packaged in a 21 gram or 40 gram tube, accompanied by 3 or 7 disposable applicators. Each applicator full of cream (i.e one dose), contains approximately 5 grams of cream (100 mg of clindamycin).

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

Protect from freezing.

Keep out of reach of children.

REGISTRATION NUMBER:

27/20.1.1/0292

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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