



# Dalacin® V

(Clindamycin Phosphate)

## Vaginal Cream

### NAME OF THE MEDICINAL PRODUCT

DALACIN® V Vaginal Cream

### QUALITATIVE AND QUANTITATIVE COMPOSITION

Clindamycin phosphate is a water-soluble ester of the semisynthetic antibiotic produced by a 7(S)-chloro-substitution of the 7(R)-hydroxyl group of the parent antibiotic lincomycin. Clindamycin vaginal cream 2%, is a semi-solid, white cream, which contains 2% clindamycin phosphate, USP, at a concentration equivalent to 20 mg clindamycin per gram. Each applicatorful of 5 grams of vaginal cream contains approximately 100 mg of clindamycin phosphate.

### PHARMACEUTICAL FORM

Vaginal cream

### CLINICAL PARTICULARS

#### THERAPEUTIC INDICATIONS

DALACIN® V Vaginal Cream 2% is indicated in the treatment of bacterial vaginosis (formerly referred to as Haemophilus vaginitis, Gardnerella vaginitis, nonspecific vaginitis, *Corynebacterium* vaginitis, or anaerobic vaginosis).

DALACIN® V Vaginal Cream can be used to treat nonpregnant women and pregnant women during their second and third trimesters.

#### POSOLOGY AND METHOD OF ADMINISTRATION

DALACIN® V Vaginal Cream:

The recommended dose is one applicatorful of clindamycin vaginal cream 2% intravaginally, preferably at bedtime, for three or seven consecutive days.

#### CONTRAINDICATIONS

Clindamycin vaginal cream is contraindicated in patients with a history of hypersensitivity to clindamycin, lincomycin or any of the components of these products. Clindamycin vaginal cream are also contraindicated in individuals with a history of antibiotic-associated colitis.

#### SPECIAL WARNINGS AND PRECAUTIONS FOR USE

The use of clindamycin vaginal products may result in the overgrowth of nonsusceptible organisms, particularly yeasts.

Orally and parenterally administered clindamycin, similar to virtually all other antibiotics, has been associated with diarrhea, and in some cases, antibiotic-associated colitis. If significant or prolonged diarrhea occurs during the use of any clindamycin vaginal product, the drug 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 clindamycin.

Clindamycin vaginal cream contains ingredients which may weaken latex or rubber products such as condoms or vaginal contraceptive diaphragms. Therefore, use of these products during treatment with clindamycin vaginal cream is not recommended.

#### PEDIATRIC USE

Safety and efficacy in pediatric patients have not been established.

#### INTERACTION 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.

#### FERTILITY, PREGNANCY AND LACTATION

In clinical trials, the use of clindamycin vaginal products in pregnant women in their second and third trimesters, and systemically administered clindamycin during their second and third trimesters, has not been associated with an increased frequency of congenital abnormalities.

If clindamycin vaginal cream is used during the second or third trimester, the possibility of fetal harm appears remote. There are, however, no adequate and well-controlled studies in pregnant women during the first trimester of pregnancy.

Clindamycin vaginal cream should be used during the first trimester of pregnancy only if clearly needed.

It is not known if clindamycin is excreted in breast milk following the use of vaginally administered clindamycin vaginal cream. Orally and parenterally administered clindamycin have been reported to appear in breast milk.

# ڈالاسین وی

## ویجینل کریم

REMOVE THIS PORTION BEFORE DISPENSING

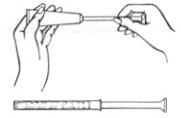
#### DIRECTIONS FOR USE

Three plastic applicators are provided with this package. They are designed to allow proper vaginal administration of the cream.

Remove cap from cream tube. Screw a plastic applicator on the threaded end of the tube.

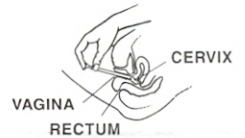
Rolling tube from the bottom, squeeze gently and force the medication into the applicator. The applicator is filled when the plunger reaches its predetermined Stopping point.

Unscrew the applicator from the tube and replace the cap.



While lying on your back, firmly grasp the applicator barrel and insert into vagina as far as possible without causing discomfort.

Slowly push the plunger until it stops. Carefully withdraw applicator from vagina, and discard applicator.



REMEMBER TO APPLY ONE APPLICATORFUL EACH NIGHT BEFORE BEDTIME, OR AS PRESCRIBED BY YOUR DOCTOR.

Therefore, a full benefit-risk assessment should be done when considering the use of either clindamycin vaginal cream in a nursing mother.

### **EFFECTS ON ABILITY TO DRIVE AND USE MACHINES**

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

### **UNDESIRABLE EFFECTS**

#### **Clinical TRIALS:**

#### **DALACIN® V Vaginal Cream:**

The safety of clindamycin vaginal cream was evaluated in both nonpregnant patients and patients during their second and third trimesters of pregnancy. The following treatment-related adverse events were reported by less than 10% of patients.

Ear and labyrinth disorders: Vertigo

Endocrine disorders: Hyperthyroidism

Gastrointestinal disorders: Generalized abdominal pain, localized abdominal pain, abdominal cramps, halitosis, abdominal distension, diarrhea, nausea, vomiting, constipation, dyspepsia, flatulence, gastrointestinal disorder

General disorders and administration site conditions: Inflammatory swelling, generalized pain

Infections and infestations: Vaginal candidiasis vulvovaginitis, trichomonal vaginitis, vaginitis/vaginal infection, urinary tract infection, candidiasis (body), fungal infection, bacterial infection, upper respiratory infection, candidiasis (skin)

Immune system disorders: Allergic reaction

Investigations: Abnormal microbiological test

Musculoskeletal and connective tissue disorders: Back pain

Nervous system disorders: Headache, dizziness, taste perversion

Pregnancy, puerperium and perinatal conditions: Abnormal labor

Reproductive system and breast disorders: Vulvovaginal disorder, menstrual disorder, vaginal pain, metrorrhagia, vaginal discharge, endometriosis, pelvic pain

Renal and urinary disorders: Dysuria, glycosuria, proteinuria

Respiratory, thoracic and mediastinal disorders: Epistaxis

Skin and subcutaneous tissue disorders: Pruritus (non-application site), rash, maculopapular rash, erythema, urticaria

### **OVERDOSE**

Vaginally applied clindamycin phosphate contained in clindamycin vaginal cream can be absorbed in sufficient amounts to produce systemic effects. In the event of overdosage, general symptomatic and supportive measures are indicated as required.

### **PHARMACOLOGICAL PROPERTIES**

#### **Pharmacodynamic properties**

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. Although

Nonetheless, clindamycin is an antimicrobial agent active *in vitro* against most strains of the following organisms that have been reported to be associated with bacterial vaginosis:

- *Bacteroides* spp.
- *Gardnerella vaginalis*
- *Mobiluncus* spp.
- *Mycoplasma hominis*
- *Peptostreptococcus* spp.

Cross resistance has been demonstrated between clindamycin and lincomycin.

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

#### Pharmacokinetic properties

Clindamycin vaginal cream:

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.

#### PRECLINICAL SAFETY DATA

Carcinogenesis:

Long term studies in animals have not been performed with clindamycin to evaluate carcinogenic potential.

Mutagenesis:

Genotoxicity tests performed included a rat micronucleus test and an Ames test. Both tests were negative.

Impairment of Fertility:

Fertility studies in rats treated orally with up to 300 mg/kg/day (31 times the human exposure based on mg/m) revealed no effects on fertility or mating ability.

#### PHARMACEUTICAL PARTICULARS

##### SHELF LIFE

24 months

##### HOW SUPPLIED

DALACIN®V vaginal Cream 2% (clindamycin phosphate) is supplied in 20gm tube with 3 disposable applicators

##### Dosage:

Use as directed by the physician.

##### Instructions:

Avoid exposure to heat, sunlight & freezing.

Store below 30°C.

Avoid contact with eyes and skin.

Keep out of the reach of children.

##### Caution:

To be sold on the prescription of a registered medical practitioner only.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات: دوا کو گرمی، سورج کی روشنی اور ٹھنڈ ہونے سے بچائیں۔

آنکھ اور جلد پر لگنے سے بچائیں۔

دوا کو 30 ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

بچوں کی پہنچ سے دور رکھیں۔

تاکید: صرف رجسٹرڈ میڈیکل پریکٹیشنر کے نسخہ پر فروخت کریں۔