PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM:

DALACIN® VC Vaginal Cream

Clindamycin phosphate

Read all of this leaflet carefully before you start using DALACIN VC:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- DALACIN VC has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT DALACIN VC CONTAINS:

The active substance is clindamycin phosphate (an antibiotic), and each 1 gram contains 20 mg of clindamycin phosphate.

The other ingredients are benzyl alcohol (preservative), cetostearyl alcohol, mineral oil, mixed fatty acid esters, polysorbate 60 (food grade), propylene glycol, sorbitan monostearate and stearic acid.

2. WHAT DALACIN VC IS USED FOR:

DALACIN VC is a vaginal cream used in the treatment of bacterial vaginosis (a bacterial infection of the vagina).

3. BEFORE YOU USE DALACIN VC:

Do not use DALACIN VC:

- if you are hypersensitive (allergic) to clindamycin, lincomycin or any of the other ingredients in DALACIN VC
- if you have a history of inflammatory bowel disease or antibiotic-associated colitis, ulcerative colitis, or regional colitis (Crohn's disease)
- if you are pregnant or breastfeeding your baby

Speak to your doctor or healthcare provider immediately if any of the above applies to you.

Take special care with DALACIN VC:

Talk to your doctor or healthcare provider before using DALACIN VC if you have diarrhoea or usually get diarrhoea when you take antibiotics.

If you develop severe or prolonged or bloody diarrhoea during or after using DALACIN VC **tell your doctor immediately** since it may be necessary to stop the treatment. This may be a sign of bowel inflammation (*pseudomembranous colitis*) which can occur following treatment with DALACIN VC.

Do not have sexual intercourse during treatment with DALACIN VC. DALACIN VC may weaken condoms and diaphragms. **Do not rely on condoms or contraceptive diaphragms when using DALACIN VC for 72 hours following treatment.**

Do not use other vaginal products such as tampons or douches (vaginal washes) during treatment with DALACIN VC.

DALACIN VC is not recommended for use in children.

Pregnancy and breastfeeding:

You should not use DALACIN VC if you are pregnant.

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice

before using DALACIN VC.

The active substance in DALACIN VC may pass into breast milk. You should not breastfeed your baby if you are on treatment with DALACIN VC.

Driving and using machinery:

No effects on the ability to drive or use machines have been seen with DALACIN VC.

Important information about some of the ingredients of DALACIN VC:

DALACIN VC contains propylene glycol and cetostearyl alcohol which may cause local skin irritation and inflammation.

Taking other medicines with DALACIN VC:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines).

If you are having a surgical procedure, tell your doctor and/or anaesthetist that you are using DALACIN VC before receiving any medicines that cause paralysis of muscle (neuromuscular blocking medicines).

4. HOW TO USE DALACIN VC:

Do not share medicines prescribed for you with any other person.

Always use DALACIN VC exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with DALACIN VC will last. Do not stop treatment early because this may cause your illness to come back.

The usual dose is one applicator full (approximately 5 grams), which should be placed into the

vagina each night at bedtime for seven consecutive nights.

Your doctor may recommend a shorter course of treatment depending on your symptoms.

Always wash your hands before using the cream.

Insertion:

- Remove the cap from the tube.
- Screw one of the disposable plastic applicators supplied on to the tube where the cap has been removed. Holding the tube from the bottom, squeeze gently and force the cream into the applicator. When the plunger stops moving, the applicator is full.
- Unscrew the applicator and replace the cap on the tube.
- Lie on your back, firmly grasp the applicator barrel, and insert gently into the vagina as far as possible without causing discomfort. Still holding the barrel, slowly push the plunger until it stops and all the cream has been expelled.
- Carefully withdraw the applicator and dispose of it. It is preferable to wrap it in paper before disposal in a waste container. Do not try to flush it down the toilet.
- Wash your hands well after applying the cream.

If you have the impression that the effect of DALACIN VC is too strong or too weak, tell your doctor or healthcare provider.

If you use more DALACIN VC than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you swallow DALACIN VC:

If you or somebody else swallows some DALACIN VC contact your doctor, who will be able to give you advice on what to do.

If you miss a dose of DALACIN VC:

If the forgotten dose is just a few hours late, use it straight away. If it is nearly time for your next application, skip the forgotten application. Do the next application at the normal time. Do not use double the amount to make up for the forgotten application but carry on using your cream at the usual times.

Effects when treatment with DALACIN VC is stopped:

Sometimes you may feel better after only a few days treatment. Even if you do feel better, do not stop using the cream until you have completed the full course of treatment.

If you have any further questions on how to use DALACIN VC, ask your doctor or healthcare provider.

5. POSSIBLE SIDE EFFECTS:

DALACIN VC can have side effects.

Not all side effects reported for DALACIN VC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your healthcare provider for advice.

Tell your doctor immediately if you develop severe, persistent or bloody diarrhoea (which may be associated with stomach pain or fever). This side effect may occur after treatment with DALACIN VC and can be a sign of serious bowel inflammation. Or if you experience a severe allergic reaction such as sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).

Tell your doctor or healthcare provider as soon as possible if you experience the following side effects that have been seen with DALACIN VC:

Frequent side effects:

- fungal and/or yeast infections
- headache
- dizziness
- change in sense of taste
- upper respiratory infection
- abdominal pain
- constipation
- diarrhoea
- nausea
- vomiting
- rash, itchiness
- back pain
- urinary tract infection
- excess sugar or protein in urine
- abnormal labour
- inflammation, pain, swelling and redness of the vulva and vagina
- menstrual disorder
- vaginal discharge

Less frequent side effects:

- bacterial infection
- light headedness
- nose bleeds
- abdominal distension
- flatulence (passing wind)
- bad breath
- skin rash
- redness of skin

- pain or difficulty in urinating
- pelvic pain
- abnormal microbiology test

Other side effects:

- overactive thyroid
- gastrointestinal disorder
- indigestion
- inflammation
- pain

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORAGE AND DISPOSAL OF DALACIN VC:

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Do not freeze.
- Do not use after the expiry date stated on the label and carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF DALACIN VC:

A 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).

8. IDENTIFICATION AND DESCRIPTION OF DALACIN VC:

A white, semi-solid cream.

9. REGISTRATION NUMBER:

27/20.1.1/0292

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

Date of registration: 22 September 1994

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