Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dalacin 2% vaginal cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains clindamycin phosphate equivalent to 20 mg or
2.0 % w/w clindamycin. Each applicator full of 5 grams of vaginal cream contains approximately 100 mg of clindamycin phosphate.

Excipients with known effect:

Dalacin Cream contains 250 mg propylene glycol in each 5 g applicator which is equivalent to 50 mg/g.
Dalacin Cream contains 160.5 mg cetostearyl alcohol in each 5 g applicator which is equivalent to 32.1 mg/g.
Dalacin Cream contains 50 mg benzyl alcohol in each 5 g applicator which is equivalent to 10 mg/g.
Dalacin Cream contains 250 mg polysorbate 60 in each 5 g applicator which is equivalent to 50 mg/g.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Vaginal cream.

White, semi-solid cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Antibiotic for use in the management of bacterial vaginosis.

4.2 Posology and method of administration

Posology
One applicator full (approximately 5 grams of cream) should be inserted intravaginally once daily for a minimum of 3 and preferably for 7 consecutive days.

Elderly:
No dose adjustment is required.

Paediatric population:
Safety and efficacy in paediatric patients have not been established.

Method of administration
For intravaginal use only using the applicator supplied. Insertion should preferably occur at bedtime.

4.3 Contraindications

Dalacin Cream is contraindicated in patients with a history of hypersensitivity to clindamycin, lincomycin or to any of the excipients listed in section 6.1. Dalacin Cream is also contraindicated in individuals with a history of inflammatory bowel disease or a history of antibiotic-associated colitis.

4.4 Special warnings and precautions for use

Differential Diagnostics

Before or after initiation of therapy with clindamycin, other infections including Trichomonas vaginalis, Candida albicans, Chlamydia trachomatis and gonococcal infections may need to be investigated by adequate laboratory tests.

Bacterial Overgrowth

The use of Dalacin Cream may result in the overgrowth of non-susceptible organisms, particularly yeasts.

Clostridium Difficile associated diarrhoea(CDAD)
Onset of symptoms suggestive of pseudomembranous colitis may occur during or after antimicrobial treatment (see section 4.8). Pseudomembranous colitis has been reported with nearly all antibacterial agents, including clindamycin, and may range in severity from mild to life-threatening. Therefore, it is important that this is considered in patients who present with diarrhoea subsequent to the administration of antibacterial agents. Moderate cases may improve following withdrawal of the drug.

Clindamycin treatment must be stopped if pseudomembranous diarrhoea occurs. An adequate antibacterial therapy should be prescribed. Drugs inhibiting peristalsis are contraindicated in this situation.

Use of Latex Condoms and Diaphragms

As with all vaginal infections, sexual intercourse during treatment with Dalacin Cream is not recommended. Latex condoms and diaphragms may be weakened if exposed to the ingredients used in clindamycin vaginal cream. The use of such products within 72 hours following treatment with clindamycin vaginal cream is not recommended as such use could be associated with diminished contraceptive efficacy or protection against sexually transmitted disease.

Use of Vaginal Products

The use of other vaginal products (such as tampons and douches) during the treatment with Dalacin Cream is not recommended.

Excipient information

Dalacin Cream contains propylene glycol, cetostearyl alcohol, benzyl alcohol and polysorbate 60 (see section 2).

Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).
Benzyl alcohol may cause allergic reactions and mild local irritation.
Polysorbate 60 may cause hypersensitivity reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Cross resistance has been demonstrated between clindamycin and lincomycin, and erythromycin and clindamycin. Antagonism has been demonstrated between clindamycin and erythromycin *in vitro*.

Systemic 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 (see section 4.9).

No information is available on concomitant use with other vaginal medications with clindamycin.

4.6 Fertility, pregnancy and lactation

Fertility
Fertility studies in rats treated orally with clindamycin revealed no effects on fertility or mating ability. No animal fertility studies have been performed using the vaginal route of administration.

Pregnancy
Use of clindamycin is not recommended during the first trimester, as there are no adequate and well-controlled studies in pregnant women over this period.

In clinical trials, use of vaginally applied Dalacin Cream in pregnant women in their second and third trimester and systemically administered clindamycin during their second and third trimester has not been associated with an increased frequency of congenital abnormalities.

Clindamycin may be used to treat pregnant women if clearly necessary during the second and third trimester of pregnancy.

Reproduction studies performed in rats and mice using oral and parenteral doses of clindamycin, ranging from 100 to 600mg/kg/day, have revealed no evidence of harm to the foetus due to clindamycin. In one mouse strain, cleft palates were observed in species treated foetuses; this response was not produced in other mouse strains or in other species, and is therefore considered to be a strain specific effect. Animal reproduction studies are not always predictive of human response.

Breast-feeding
Clindamycin is excreted in human milk after intravenous and oral dosing (see section 5.2) and effects (e.g. diarrhoea, blood in stool and rash) have been shown in breastfed newborns/infants of treated women. Concentrations of clindamycin in milk after daily dosing with Dalacin vaginal cream are unknown but are expected to be lower than those reported after systemic administration.

A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from clindamycin therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

4.7 Effects on ability to drive and use machines

Clindamycin has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Table 1 below lists the adverse reactions identified through clinical trial experience and post-marketing surveillance by system organ class and frequency. Adverse reactions identified from post-marketing experience are included in italics. The frequency grouping is defined using the following convention: Very common (≥1/10); Common (≥ 1/100 to <1/10); Uncommon (≥1/1,000 to <1/100); Rare (≥ 1/10,000 to <1/1,000); Very Rare (< 1/10,000); and Not known (cannot be estimated from the available data). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

The safety of clindamycin vaginal cream was evaluated in both non pregnant 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.

Table 1:

System Organ Class	**Very Common ≥ 1/10**	**Common ≥ 1/100 to <1/10**	**Uncommon ≥ 1/1 000 to <1/100**	**Rare ≥ 1/10 000 to <1/1 000**	**Very Rare < 1/10 000**	**Not Known (cannot be estimated from available data)**
Infections and infestations	Vulvovaginal candidiasis	Fungal infection, candida infection Vulvovaginitis, Urinary tract infection, Upper respiratory tract infection	Bacterial infection, Vaginal infection, Vulvaginitis trichomonal			Skin candida *Pseudomembranous colitis* (see section 4.4)
Immune System Disorders			Hypersensitivity			
Endocrine disorders						Hyperthyroidism
Nervous System Disorders		Headache, Dizziness, Dysgeusia				

Ear and labyrinth disorders			Vertigo			
Respiratory, thoracic and mediastinal disorders			Epistaxis			
Gastrointestinal Disorders		Abdominal pain, Constipation, Diarrhoea, Nausea, Vomiting	Abdominal distension, Breath odour Flatulence			Gastrointestinal disorder, Dyspepsia
Skin and Subcutaneous Tissue Disorders		Pruritus(non-applicable site), Rash	Urticaria, Erythema			Rash maculopapular
Musculoskeletal and connective tissue disorders		Back pain				
Renal and urinary disorders		Glycosuria Proteinuria	Dysuria			
Pregnancy, puerperium and perinatal conditions		Abnormal labour				
Reproductive system and breast disorders		Vulvovaginal disorder, Menstrual disorder, Vulvovaginal pain, Metrorrhagia, Vaginal discharge, Vulvovaginal discomfort	Pelvic pain			Endometriosis
General disorders and administration site conditions						Inflammation, Pain
Investigations						Microbiology test abnormal

The following medically significant adverse events in Table 2 were reported during therapy with systemic formulations of clindamycin. Frequency reported: Very rare <1/10,000.

Table 2:

System Organ Class	**Very Common ≥ 1/10**	**Common ≥ 1/100 to <1/10**	**Uncommon ≥ 1/1 000 to <1/100**	**Rare ≥ 1/10 000 to <1/1 000**	**Very Rare < 1/10 000**	**Not Known (cannot be estimated from available data)**
Blood and Lymphatic System Disorders					Agranulocytosis Leukopenia Neutropenia Thrombocytopenia	
Immune System Disorders					Anaphylactoid reaction	Drug reaction with eosinophilia and systemic symptom (DRESS)
Hepatobiliary Disorders					Jaundice	
Skin and Subcutaneous					Toxic epidermal necrolysis	Acute generalised exanthematous pustulosis

Tissue Disorders					Stevens-Johnson syndrome Erythema multiforme	(AGEP)

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance. Website: www.hpra.ie.

4.9 Overdose

There are no reports of overdose with clindamycin. Vaginally applied Dalacin 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.

Accidental oral intake can lead to effects comparable with those of therapeutic concentrations of orally administered clindamycin.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Gynaecological anti-infectives and antiseptics
ATC Code: G01AA10

Mode of action
Clindamycin is a lincosamide antibiotic that inhibits bacterial protein synthesis at the level of the bacterial ribosome. It binds preferentially to the 50S ribosomal subunit and affects the translation process.

Resistance
Resistance to clindamycin is most often due to modification of the target site on the ribosome, usually by chemical modification of RNA bases or by point mutations in RNA. Cross resistance has been demonstrated in vitro between clindamycin and other lincosamides, macrolides and streptogramins B.

Spectrum of activity
Clindamycin is 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.

5.2 Pharmacokinetic properties

Following a once a day intravaginal dose of 5 g of Dalacin Cream 2%, equivalent to a 100mg daily intravaginal dose of clindamycin, administered for 7 days to 6 healthy female volunteers approximately 4% (range 0.6% to 11%) of the administered dose of clindamycin 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 5 g of Dalacin Cream 2%, equivalent to a 100mg daily intravaginal dose of clindamycin, 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 Dalacin Cream 2%. The systemic half-life was 1.5 to 2.6 hours.
Clindamycin is widely distributed in body fluids and tissues including bone and bile, but it does not reach the cerebrospinal fluid in significant concentrations. It diffuses across the placenta into the foetal circulation and appears in breast milk. Concentrations in human breast milk have been reported to be up to 3.8 microgram/mL shortly after a 600 mg IV dose, falling to about 1 microgram/mL at about 2h. The Cmax after oral dosing is not known but milk levels up to 1.2 microgram/mL have been reported after a 150 mg oral dose. Levels achieved in milk after daily intravaginal dosing with 5 g Dalacin Cream 2% are unknown.

5.3 Preclinical safety data

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

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

Reproductive toxicity
Fertility studies in rats treated orally with up to 300 mg/kg/day (31 times the human exposure based on mg/m2) revealed no effects on fertility or mating ability.

In oral embryo-foetal development studies in rats and subcutaneous embryo-foetal development studies in rats and rabbits, no developmental toxicity was observed except at doses that produced maternal toxicity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitan stearate
Polysorbate 60
Propylene glycol (E1520)
Stearic acid
Cetostearyl alcohol
Mixed fatty acid esters/cetyl palmitate
Mineral oil (viscosity 180)
Benzyl alcohol (E1519)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25ºC. Do not freeze.

6.5 Nature and contents of container

Collapsible, laminate tube (consisting of LDPE, ethylene co-polymer, paper and aluminium foil) with polypropylene cap containing 20 gram or 40 gram of cream, packed together with a leaflet, in a cardboard box.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Pfizer Healthcare Ireland Unlimited Company
The Watermarque Building
Ringsend Road
Dublin 4
D04 K7N3
Ireland

8 MARKETING AUTHORISATION NUMBER

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