Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dalacin C Phosphate 150 mg/ml Concentrate for Solution for injection/infusion, 2ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution contains clindamycin phosphate equivalent to 150 mg clindamycin, giving 300 mg clindamycin per ampoule.

Excipients with known effect
Each ml of solution contains 9 mg of benzyl alcohol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for solution for injection/infusion.
Clear colourless sterile solution with a pH of 5.5-7.0

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the management of serious infections due to organisms susceptible to this anti-infective.
Clindamycin does not penetrate the blood/brain barrier in therapeutically effective quantities.

4.2 Posology and method of administration

Posology
Parenteral (IM or IV administration).
Dalacin C Phosphate **must** be diluted prior to IV administration and should be infused slowly and should be infused over at least 10-60 minutes (see ' **Dilution for IV use and IV infusion rates**' at the end of the section).
Dalacin C Phosphate IM administration should be used undiluted.

Adult:
The usual daily adult dosage of Dalacin C Phosphate for infections of the intra-abdominal area, female pelvis, and other complicated or serious infections is 1800-2700 mg given in 2, 3, or 4 equal doses. Less complicated infections due to more susceptible microorganisms may respond to lower doses such as 1200-1800 mg/day administered in 3 or 4 equal doses. Doses of up to 4800 mg daily have been used successfully.

Single IM injections of greater than 600 mg are not recommended nor is administration of more than 1.2 g in a single one-hour infusion.

Alternatively, the drug may be administered in the form of a single rapid infusion of the first dose followed by continuous IV infusion.

Paediatric population
Clindamycin should be dosed based on total body weight regardless of obesity. The total daily dose should not exceed the maximum recommended daily dose for adults.

Children (over 1 month of age): Serious infections: 15-25 mg/kg/day in three or four equal doses.

More severe infections: 25-40 mg/kg/day in three or four equal doses. In severe infections it is recommended that children be given no less than 300 mg/day regardless of body weight.

*Neonates (under 1 month of age):*Dalacin C Phosphate (IM or IV administration): 15-20 mg/kg/day in 3 or 4 equal doses. The lower dosage may be adequate for small premature infants (see section 4.4).

Dosage in Elderly: Pharmacokinetic studies with Dalacin C Phosphate have shown no clinically important differences between young and elderly subjects with normal hepatic function and normal (age-adjusted) renal function after oral or intravenous administration. Therefore, dosage adjustments are not necessary in the elderly with normal hepatic function and normal (age-adjusted) renal function(see section 5.2).

Dosage in Renal Impairment: Dalacin C Phosphate dosage modification is not necessary in patients with renal insufficiency.

Dosage in Hepatic Impairment: Dalacin C Phosphate dosage modification is not necessary in patients with hepatic insufficiency.

Method of administration

Dilution for IV use and IV infusion rates
The concentration of clindamycin in diluent for infusion should not exceed 18 mg per mL and INFUSION RATES SHOULD NOT EXCEED
30 MG PER MINUTE. The usual infusion rates are as follows:

Dose	Diluent	**Time**
300 mg	50 mL	10 min
600 mg	50 mL	20 min
900 mg	50-100 mL	30 min
1200 mg	100 mL	40 min

4.3 Contraindications

Clindamycin is contraindicated in patients previously found to be sensitive to lincomycin, clindamycin, any component of the formulation, or to any of the excipients listed in section 6.1.

Use in patients with diarrhoea or intestinal inflammatory disease.

4.4 Special warnings and precautions for use

Hypersensitivity
Severe hypersensitivity reactions, including severe skin reactions such as drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP) have been reported in patients receiving clindamycin therapy. If a hypersensitivity or severe skin reaction occurs, clindamycin should be discontinued and appropriate therapy should be initiated (see sections 4.3 and 4.8).

Excipient information
Benzyl alcohol
Dalacin C Phosphate contains benzyl alcohol (see section 2). The preservative benzyl alcohol may cause hypersensitivity reactions. Intravenous administration of benzyl alcohol has been associated with serious adverse events and deaths in paediatric patients including neonates ("gasping syndrome"). Although normal therapeutic doses of this product ordinarily deliver amounts of benzyl alcohol that are substantially lower than those reported in association with the "gasping syndrome", the minimum amount of benzyl alcohol at which toxicity may occur is not known. Benzyl alcohol containing formulations should only be used in neonates if it is necessary and if there are no alternatives possible. Premature and low-birth weight infants may be more likely to develop toxicity. Benzyl alcohol containing formulations should not be used for more than one week in children under 3 years of age, unless necessary. It is important to consider the total quantity of benzyl alcohol received from all sources, and high volumes should be used with caution and only if necessary, especially in patients with liver or kidney impairment, as well as in pregnant or breast-feeding women, because of the risk of accumulation and toxicity (metabolic acidosis).

Sodium
Dalacin C Phosphate contains less than 1 mmol sodium (23 mg) in each 2 ml ampoule, that is to say essentially 'sodium free'.

Precautions
Clostridium Difficile associated diarrhoea

Dalacin C Phosphate should only be used in the treatment of serious infections. In considering the use of Dalacin C Phosphate, the practitioner should bear in mind the type of infection and the potential hazard of the diarrhoea which may develop, since cases of colitis have been reported during, or even two or three weeks following, the administration of Dalacin C Phosphate. Studies indicate a toxin(s) produced by clostridia (especially *Clostridium difficile)* is the principal direct cause of antibiotic-associated colitis. Colitis is a disease which has a clinical spectrum from mild, watery diarrhoea to severe, persistent diarrhoea, leucocytosis, fever severe abdominal cramps, which may be associated with the passage of blood and mucus. If allowed to progress, it may product peritonitis, shock and toxic megacolon. This may be fatal.

The disease is likely to follow a more severe course in older patients or patients who are debilitated. Diagnosis is usually made by recognition of the clinical symptoms, but can be substantiated by endoscopic demonstration of pseudomembranous colitis. The presence of the disease may be further confirmed by culture of the stool for *Clostridia difficile* on selective media and assay of the stool specimen for the toxin(s) of *C. Difficile*.

Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *Clostridium difficile*. This has been reported with use of nearly all antibacterial agents, including clindamycin. *Clostridium difficile* produces toxins A and B which contribute to the development of *Clostridium difficile* associated diarrhoea (CDAD) and is a primary cause of 'antibiotic-associated colitis'.

It is important to consider the diagnosis of CDAD in patients who present with diarrhoea subsequent to the administration of antibacterial agents. This may progress to colitis, including pseudomembranous colitis (see section 4.8), which may range from mild to fatal colitis. If antibiotic-associated diarrhoea or antibiotic-associated colitis is suspected or confirmed, ongoing treatment with antibacterial agents, including clindamycin, should be discontinued and adequate therapeutic measures should be initiated immediately. Drugs inhibiting peristalsis are contraindicated in this situation.

Caution should be used when prescribing Dalacin C Phosphate to individuals with a history of gastro-intestinal disease, especially colitis.

Non-susceptible organisms
The use of clindamycin phosphate may result in overgrowth of non-susceptible organisms, particularly yeasts.

Prolonged administration of Dalacin C Phosphate, as with any anti-infective, may result in super-infection due to organisms resistant to Dalacin C Phosphate.
Diffusion into cerebrospinal fluid
Since clindamycin does not diffuse adequately into cerebrospinal fluid, the drug should not be used in the treatment of meningitis.

Liver and kidney function tests during prolonged therapy
If therapy is prolonged, liver and kidney function and haematology tests should be performed. Such monitoring is also recommended in infants under the age of one year. Safety and appropriate dosage in infants less than one month old have not been established.

Acute kidney injury, including acute renal failure, has been reported infrequently. In patients suffering from pre-existing renal dysfunction or taking concomitant nephrotoxic drugs, monitoring of renal function should be considered (see section 4.8).

Cross resistance
Attention should also be paid to the possibility of cross resistance between macrolides and lincosamides for some individual bacterial strains (see section 5.1).

Use in patients with atopic syndrome
The drug should be used with caution in patients with the atopic syndrome, particularly with asthma.

Use in patients taking oral contraceptives
Antibiotics can reduce the efficacy of the oral contraceptive pill. Additional contraceptive precautions should be taken during treatment.

Bolus injection
Clindamycin phosphate should not be injected intravenously undiluted as a bolus, but should be infused over at least 10-60 minutes as directed in section 4.2.

4.5 Interaction with other medicinal products and other forms of interaction

Dalacin C Phosphate administered by injection 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.

Cross-resistance can be demonstrated with lincomycin.

In-vitro compatibility studies monitored for 24 hours at room temperature using a concentration no greater than 6 mg/ml have demonstrated no inactivation or physical incompatibility with the use of Dalacin C Phosphate in i.v solutions containing sodium chloride, glucose or potassium usually used clinically.

The following drugs are physically incompatible with Dalacin C Phosphate: ampicillin, phenytoin sodium, barbiturates, aminophylline, calcium gluconate, magnesium sulphate, ceftriaxone sodium, diphenylhydantoin, idarubicin, hydrochloride, and ranitidine hydrochloride. Solutions of clindamycin salts have a low pH and incompatibility may reasonably be expected with alkaline preparations or with drugs unstable at low pH.

Vitamin K antagonists
Increased coagulation tests (PT/INR) and/or bleeding have been reported in patients treated with clindamycin in combination with a vitamin K antagonist (e.g. warfarin, acenocoumarol and fluindione). Coagulation tests, therefore, should be frequently monitored in patients treated with vitamin K antagonists.

Co-administration of clindamycin with inhibitors of CYP3A4 and CYP3A5. Clindamycin is metabolized predominantly by CYP3A4, and to a lesser extent by CYP3A5, to the major metabolite clindamycin sulfoxide and minor metabolite N-desmethylclindamycin. Therefore inhibitors of CYP3A4 and CYP3A5 may reduce
clindamycin clearance and inducers of these isoenzymes may increase clindamycin clearance. In the presence of strong CYP3A4 inducers such as rifampicin, monitor for loss of effectiveness.
In vitro studies indicate that clindamycin does not inhibit CYP1A2, CYP2C9, CYP2C19, CYP2E1 or CYP2D6 and only moderately inhibits CYP3A4. Therefore, clinically important interactions between clindamycin and co-administered drugs metabolized by these CYP enzymes are unlikely.

4.6 Fertility, pregnancy and lactation

Pregnancy
Oral and subcutaneous reproductive toxicity studies in rats and rabbits revealed no evidence of impaired fertility or harm to the foetus due to clindamycin, except at doses that caused maternal toxicity. Animal reproduction studies are not always predictive of human response.

Clindamycin crosses the placenta in humans. After multiple doses, amniotic fluid concentrations were approximately 30% of maternal blood concentrations.

Dalacin C Phosphate contains benzyl alcohol as a preservative. Benzyl alcohol can cross the placenta, (see section 4.4).

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 and well-controlled studies in pregnant women during the first trimester of pregnancy.

Clindamycin should be used in pregnancy only if clearly needed.

Breast-feeding
Clindamycin is excreted in human milk (see section 5.2) and effects (e.g. diarrhoea, blood in stool and rash) have been shown in breastfed newborns/infants of treated women.

Dalacin C Phosphate contains benzyl alcohol as a preservative (see section 4.4).

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.

Fertility

Fertility studies in rats treated orally with clindamycin revealed no effects on fertility or mating ability.

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

The table below lists the adverse reactions identified through clinical trial experience and post-marketing surveillance by system organ class and frequency. 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.

System Organ Class	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	pseudomembranous colitis[*#]				*clostridium difficile* colitis*, vaginal infection*
Blood and Lymphatic System Disorders					agranulocytosis*, neutropenia*, thrombocytopenia*, leukopenia*, eosinophilia
Immune System Disorders					anaphylactic shock*, anaphylactoid reaction*, anaphylactic reaction*, hypersensitivity*
Nervous System Disorders		dysgeusia			
Cardiac Disorders		cardio-respiratory arrest[†§],			
Vascular Disorders	thrombophlebitis[†]	hypotension[†§]			
Gastrointestinal Disorders		diarrhoea, nausea			abdominal pain, vomiting
Hepatobiliary Disorders					jaundice*
Skin and Subcutaneous Tissue Disorders	rash maculopapular	urticaria erythema multiforme, pruritus			toxic epidermal necrolysis (TEN)*, Stevens Johnson syndrome (SJS)*, drug reaction with eosinophilia and systemic symptom (DRESS)*, acute generalised exanthematous pustulosis (AGEP)*, angioedema*, dermatitis exfoliative*, dermatitis bullous*, rash morbilliform*
Renal and urinary disorders					acute kidney injury[#]
General Disorders and Administrative Conditions		pain[†], injection site abscess[†]			injection site irritation[†*]
Investigations	liver function test abnormal				

* ADR identified post-marketing.
† ADRs apply only to injectable formulations.

See section 4.4.
§ Rare instances have been reported following too rapid intravenous administration (see section 4.2).

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

In cases of overdosage no specific treatment is indicated.

The serum biological half-life of clindamycin is 2.4 hours. Haemodialysis and peritoneal dialysis are not effective in removing clindamycin from the serum. If an allergic adverse reaction occurs, therapy should be with the usual emergency treatments, including corticosteroids, adrenaline and antihistamines.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacodynamic properties
Pharmacotherapeutic group: Anti-infectives or systemic use, ATC Code: J01FF01.
Mechanism of action
Clindamycin is a lincosamide antibiotic with a primarily bacteriostatic action against gram-positive aerobes and a wide range of anaerobic bacteria. Lincosamides such as clindamycin bind to the 50S subunit of the bacterial ribosome similarly to macrolides such as erythromycin and inhibit the early stages of protein synthesis. The action of Dalacin C Phosphate is predominantly bacteriostatic although high concentrations may be slowly bactericidal against sensitive strains.
Although Dalacin C Phosphate is inactive *in vitro*, rapid *in vivo* hydrolysis converts this compound to the antibacterially active clindamycin. At usual doses, clindamycin exhibits bacteriostatic activity *in vitro*.

Pharmacodynamic effects
Efficacy is related to the time period over which the agent level is above the minimum inhibitory concentration (MIC) of the pathogen (%T/MIC).

Resistance
Resistance to clindamycin is most often due to mutations at the rRNA antibiotic binding site or methylation of specific nucleotides in the 23S RNA of the 50S ribosomal subunit. These alterations can determine *in vitro* cross resistance to macrolides and streptogramins B (MLSB phenotype). Resistance is occasionally due to alterations in ribosomal proteins. Resistance to clindamycin may be inducible by macrolides in macrolide-resistant bacterial isolates.

Inducible resistance can be demonstrated with a disk test (D-zone test) or in broth. Less frequently encountered resistance mechanisms involve modification of the antibiotic and active efflux. There is complete cross resistance between clindamycin and lincomycin. As with many antibiotics, the incidence of resistance varies with the bacterial species and the geographical area. The incidence of resistance to clindamycin is higher among methicillin-resistant staphylococcal isolates and penicillin-resistant pneumococcal isolates than among organisms susceptible to these agents.

Most gram-negative aerobic bacteria, including the Enterobacteriaceae, are resistant to Dalacin C Phosphate. Dalacin C Phosphate demonstrates cross-resistance with lincomycin. When tested by in vitro methods, some staphylococcal strains originally resistant to erythromycin rapidly developed resistance to Dalacin C Phosphate. The mechanisms for resistance are the same as for erythromycin, namely methylation of the ribosomal binding site, chromosomal mutation of the ribosomal protein and in a few staphylococcal isolates enzymatic inactivation by a plasmid-mediated adenyltransferase.

Antimicrobial activity
Dalacin C Phosphate has been shown to have *in vitro* activity against most isolates of the following organisms:

Aerobic bacteria
Gram-positive bacteria

- *Staphylococcus aureus (methicillin-susceptible isolates)*

- *Coagulase-negative staphylococci (methicillin-susceptible isolates)*
- *Streptococcus pneumoniae (penicillin-susceptible isolates)*
- *Beta-hemolytic streptococci groups A, B, C, and G*
- *Viridans group streptococci*
- *Corynebacterium spp.*

Gram-negative bacteria

- *Chlamydia trachomatis*

Anaerobic bacteria
Gram-positive bacteria

- *Actinomyces spp.*
- *Clostridium spp. (except Clostridium difficile)*
- *Eggerthella (Eubacterium) spp.*
- *Peptococcus spp.*
- *Peptostreptococcus spp. (Finegoldia magna, Micromonas micros)*
- *Propionibacterium acnes*

Gram-negative bacteria

- *Bacteroides spp.*
- *Fusobacterium spp.*
- *Gardnerella vaginalis*
- *Prevotella spp.* Fungi
- *Pneumocystis jirovecii* Protozoans
- *Toxoplasma gondii*
- *Plasmodium falciparum*

Breakpoints

The prevalence of acquired resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent in at least some types of infections is questionable. Particularly in severe infections or therapy failure microbiological diagnosis with verification of the pathogen and its susceptibility to clindamycin is recommended.

Resistance is usually defined by susceptibility interpretive criteria (breakpoints) established by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) for systemically administered antibiotics.

The European Committee on Antimicrobial Susceptibility Testing (EUCAST) breakpoints are presented below.

Table 1. EUCAST Susceptibility Interpretive Criteria for Clindamycin				
	MIC breakpoints (mg/L)		**Zone diameter breakpoints (mm)[a]**	
Organism	**S ≤**	**R >**	**S ≥**	**R <**
Staphylococcus spp.	0.25	0.5	22	19
Streptococcus Groups A, B, C and G	0.5	0.5	17	17
Streptococcus pneumoniae	0.5	0.5	19	19
Viridans group streptococci	0.5	0.5	19	19
Gram-positive anaerobes	4	4	NA	NA
Gram-negative anaerobes	4	4	NA	NA
Corynebacterium spp.	0.5	0.5	20	20
[a]Disk content 2 µg of clindamycin				

NA=not applicable; S=susceptible; R=resistant				

EUCAST QC ranges for MIC and disk zone determinations are in the table below.

Table 2. EUCAST Acceptable Quality Control (QC) Ranges for Clindamycin to be Used in Validation of Susceptibility Test Results		
QC Strain	**Minimum Inhibitory Concentration Range (mcg/mL)**	**Disk Diffusion Range (Zone Diameters in mm)**
Staphylococcus aureus ATCC 29213	0.06–0.25	23-29
Streptococcus pneumoniae ATCC 49619	0.03–0.125	22-28
ATCC® is a registered trademark of the American Type Culture Collection		

5.2 Pharmacokinetic properties

General characteristics of active substance

Following parenteral administration, the biologically inactive clindamycin phosphate is hydrolysed to clindamycin. When the equivalent of 300 mg of Dalacin C Phosphate is injected intramuscularly, a mean peak plasma concentration of 6 microgram/ml is achieved within three hours; 600 mg gives a peak concentration of 9 microgram/ml. In children, peak concentration may be reached within one hour. When the same doses are infused intravenously, peak concentrations of 7 and 10 micrograms per ml respectively are achieved by the end of infusion.

Clindamycin is widely distributed in body fluids and tissues including bone, but it does not reach the cerebrospinal fluid in significant concentrations.

Concentrations in human breast milk have been reported to be up to 3.8 µg/mL shortly after a 600 mg IV dose, falling to about 1 µg/mL at about 2 h. The Cmax after oral dosing is not known but milk levels up to 1.2 µg/mL have been reported after a 150 mg oral dose. It diffuses across the placenta into the foetal circulation and appears in breast milk.

High concentrations occur in bile. It accumulates in leucocytes and macrophages. Over 90% of clindamycin in the circulation is bound to plasma proteins. *In vitro* studies in human liver and intestinal microsomes indicated that clindamycin is predominantly oxidized by CYP3A4, with minor contribution from CYP3A5, to form clindamycin sulfoxide and a minor metabolite, N-desmethylclindamycin. The half-life is 2 to 3 hours, although this may be prolonged in pre-term neonates and patients with severe renal impairment.

Clindamycin undergoes metabolism, to the active *N*-demethyl and sulfoxide metabolites and also some inactive metabolites. About 10% of the drug is excreted in the urine as active drug or metabolites and about 4% in the faeces; the remainder is excreted as inactive metabolites. Excretion is slow and takes place over several days, it is not effectively removed from the blood by dialysis.

Obese paediatric patients aged 2 to 18 years and obese young adults aged 18 to 20 years:
An analysis of pharmacokinetic data in paediatric patients (2 to 18 years) and young adults (18 to 20 years) demonstrated that the clearance and volume of distribution of clindamycin, when normalized to total body weight, are comparable between obese and non-obese patients.

5.3 Preclinical safety data

Carcinogenicity

Long term studies in animals have not been performed with Dalacin C Phosphate to evaluate carcinogenic potential.

Mutagenicity

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

Reproductive toxicity

Fertility studies in rats treated orally with up to 300 mg/kg/day (approximately 1.1 times the highest recommended adult human dose based on mg/m^2) 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

Benzyl alcohol (E1519)
Disodium edetate
Sterilised water for injections
Sodium hydroxide (for pH-adjustment)
Dilute hydrochloric acid (for pH-adjustment)

6.2 Incompatibilities

Solutions of clindamycin salts have a low pH and incompatibilities may reasonably be expected with alkaline preparations or drugs unstable at low pH. Incompatibility has been reported with: ampicillin sodium, aminophylline, barbiturates, calcium gluconate, ceftriaxone sodium, ciprofloxacin idarubicin hydrochloride, magnesium sulfate, phenytoin sodium and ranitidine hydrochloride.

6.3 Shelf life

Dalacin C Phosphate has a shelf-life of 24 months. Use diluted solution immediately.

6.4 Special precautions for storage

Do not store above 25 °C. Do not refrigerate or freeze.

6.5 Nature and contents of container

Type 1 flint colourless glass ampoule containing 2 ml sterile, aqueous solution. 5 ampoules packed in a cardboard carton, together with a leaflet.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Dalacin C Phosphate has been known to be physically and chemically compatible for at least 24 hours in dextrose 5% water and sodium chloride injection solutions containing the following antibiotics in usually administered concentrations: Amikacin sulfate, aztreonam, cefamandole nafate, cephazolin sodium, cefotaxime sodium, cefoxitin sodium, ceftazidime sodium, ceftizoxime sodium, gentamicin sulfate, netilmicin sulfate, piperacillin and tobramycin.

The compatibility and duration of stability of drug admixtures will vary depending upon concentration and other conditions.

Dalacin C Phosphate is a single dose use only and any unused contents should be discarded.

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
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Ireland

8 MARKETING AUTHORISATION NUMBER

PA0822/120/002

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first authorisation: 9th September 1976
Date of latest renewal: 22nd May 2006

10 DATE OF REVISION OF THE TEXT

December 2024