SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Clindamycin 150 mg/ml solution for injection/infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution contains 150 mg of clindamycin (as clindamycin phosphate).

Each ampoule of 2 ml solution contains 300 mg clindamycin (as clindamycin phosphate).

Each ampoule of 4 ml solution contains 600 mg clindamycin (as clindamycin phosphate).

Excipient with known effect

Each ml of solution contains 6.5 mg sodium.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection/infusion.

Clear, colourless to almost colourless solution, practically free from visible particles.

pH of solution 5.5 – 7.0

Osmolality 700 to 830 mOsmol/kg

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Clindamycin 150 mg/ml solution for injection/infusion is indicated for the treatment of the following severe infections caused by clindamycin sensitive bacteria in adults and children from the age of 1 month (see sections 4.2 and 5.1):

- Bone and joint infections
- Chronic sinusitis caused by anaerobic microorganisms
- Infections of the lower respiratory tract
- Complicated intra-abdominal infections
- Pelvic and female genital infections
- Complicated skin and soft tissue infections.

Clindamycin may be used for prophylaxis in surgery in case of allergy to beta-lactams.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration

The dosage and method of administration should be determined depending on the severity of infection, patient condition and the susceptibility of the microorganism causing the disease. Local guidance should be taken into consideration.

Posology

Adults

Intramuscular or intravenous administration: 1200-2700 mg/day divided into 2-4 doses.

The usual dose for infections of intra-abdominal area, female pelvic area or other severe infections is 2400-2700 mg daily IV or IM administered in 2, 3 or 4 equal doses (without exceeding the maximum recommended single dose of 1200 mg IV or 600 mg IM).

For the treatment of less complicated infections due to more susceptible microorganisms that may respond to lower doses: the dose is 1200-1800 mg daily IV or IM administered in 3 or 4 equal doses.

In life-threatening infections the intravenous dose may be increased up to 4800 mg daily.

Prophylaxis in surgery

The dosage should be determined depending on type and duration of the surgical procedure.

The usual dose is 600-900 mg given every 4-8 hours, until the end of the procedure.

Paediatric population

Children over 1 month to 12 years of age

20-40 mg/kg daily IV or IM administered in 3 or 4 equal doses (see section 4.4).

The dose of clindamycin in children should be based on total body weight regardless of obesity (see section 5.2). In severe infections, it is recommended that children be given no less than 300 mg/day regardless of body weight. The total daily dose should not exceed the maximum recommended daily dose for adults.

Adolescents over 12 years of age

Doses in adolescents over 12 years of age should be the same as in adults, taking into account possible dose adjustments based on liver function. In underweight adolescent patients, between the ages of 12 and 18 it is not recommended to exceed the maximum dose of 40 mg/kg/day. The total daily dose should not exceed the maximum recommended daily dose for adults.

Infants less than 1 month of age

The safety and efficacy of Clindamycin in infants less than one month of age have not been established. No data are available.

Elderly patients

No dose adjustment is required in the elderly with normal hepatic and renal function (see section 5.2).

Hepatic impairment

The elimination half-life is prolonged in patients with moderate to severe hepatic impairment (see sections 4.4 and 5.2). However, when clindamycin is administered every 8 hours, accumulation occurs only rarely. In patients with severe hepatic impairment, it is recommended to monitor hepatic function and the patient's progress, and monitoring of plasma levels of clindamycin is recommended, where possible. Depending on the results, the dose or dosing intervals should be adjusted, if necessary.

Renal impairment

The elimination half-life is prolonged in patients with renal impairment (see sections 4.4 and 5.2). However, no dose adjustment is necessary in patients with mild to moderate renal impairment. In patients with severe renal impairment, it is recommended to monitor renal function and the patient's progress.

Clindamycin cannot be removed by haemodialysis. Therefore, no additional dose is necessary before or after haemodialysis.

Method of administration

Intramuscular injection (IM) or intravenous infusion (IV).

For intramuscular administration, Clindamycin should be used undiluted. Intramuscular administration of more than 600 mg at once is not recommended.

Intramuscular administration is indicated when intravenous infusion is not possible for any reasons.

For intravenous administration, Clindamycin **must be diluted prior IV administration** and should be infused over at least 10-60 minutes. The concentration should not exceed 18 mg clindamycin per ml solution and the infusion rate should not exceed 30 mg/min. **It must never be given as intravenous bolus injection** (may cause serious adverse events, see section 4.8). Intravenous infusions of more than 1200 mg in one hour are not recommended.

Table 1 The usual infusion rates

Dose	Diluent	Concentration of clindamycin	Minimum infusion-time
300 mg	50 ml	6 mg/ml	10 minutes
600 mg	50 ml	12 mg/ml	20 minutes
900 mg	50-100 ml	9 mg/ml to 18 mg/ml	30 minutes
1200 mg	100 ml	12 mg/ml	40 minutes

For compatible diluents, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substance, lincomycin or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Hypersensitivity reactions

Severe hypersensitivity reactions can occur even after the first administration. In case hypersensitivity reaction occur, treatment with clindamycin must be discontinued immediately and the appropriate standard emergency measures initiated (see sections 4.3 and 4.8).

Under certain circumstances, clindamycin therapy may be an alternative form of treatment in patients with a penicillin allergy (penicillin hypersensitivity). There have been no reports of a cross-allergy between clindamycin and penicillin and, based on the structural differences between the substances, this is not to be expected. However, in individual cases, information does exist on anaphylaxis (hypersensitivity) towards clindamycin in persons with an already existing penicillin allergy. This should be taken into consideration in a course of clindamycin treatment in patients with a penicillin allergy.

Severe cutaneous adverse reactions

Severe cutaneous adverse reactions such as drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and acute generalised exanthematous pustulosis (AGEP), which could be life-threatening or fatal, have been reported in patients receiving clindamycin. These can occur even after the first administration. If signs and symptoms of severe skin reactions appear, treatment with clindamycin must be discontinued immediately and the appropriate standard emergency measures initiated. If the patient has developed a serious reaction such as DRESS, SJS, TEN or AGEP with the use of clindamycin, treatment with clindamycin must not be restarted in this patient at any time (see sections 4.3 and 4.8).

Gastrointestinal disorders

Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *Clostridioides difficile*. This has been reported with use of nearly all antibacterial agents, including clindamycin. *C. difficile* produces toxins A and B which contribute to the development of *C. 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 develop 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. Medicinal products inhibiting peristalsis are contraindicated in this situation.

Clindamycin therapy has been associated with a pseudomembranous colitis during and until 2 to 3 weeks after the treatment with clindamycin which may be fatal, and which is associated with severe and persistent diarrhoea. Care should be taken when prescribing clindamycin to a patient who has a tendency towards gastrointestinal illnesses, in particular colitis. Antibiotic-associated colitis and diarrhoea are more frequent and severe in debilitated and/or elderly patients (> 60 years).

Disturbances in neuromuscular transmission

Caution should be exercised in patients with disturbances in neuromuscular transmission (e.g. myasthenia gravis, Parkinson’s disease) since clindamycin has been associated with neuromuscular blockade and prolongation of blockage (see

sections 4.5 and 4.8). *In vitro,* clindamycin has been shown to inhibit nicotinic acetylcholine receptors.

Hepatic and renal impairment

During long-term treatment, liver and kidney function should be regularly monitored.

The elimination half-life is prolonged in patients with renal impairment and patients with moderate to severe hepatic impairment (see sections 4.2 and 5.2).

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).

Overgrowth of non-susceptible organisms

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

Diffusion into cerebrospinal fluid

Since clindamycin does not diffuse adequately into cerebrospinal fluid, it should not be used in the treatment of meningitis.

Other

Caution should be exercised in patients with atopic diseases.

Sodium

This medicinal product contains 6.5 mg sodium per ml of solution, equivalent to 0.33 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

4.5 Interaction with other medicinal products and other forms of interaction

Neuromuscular blocking agents

Clindamycin may potentiate the action of neuromuscular blocking agents. Therefore, it should be used with caution in patients receiving such agents.

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 antagonists (e.g. warfarin, acenocoumarol and fluindione). Coagulation tests should, therefore, be frequently monitored in patients treated with vitamin K antagonists.

Other antibacterial agents

Antagonism has been demonstrated between clindamycin and erythromycin *in vitro*. Because of possible clinical significance, these two medicines should not be administered concurrently.

CYP enzyme inhibitors and inducers

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 decrease clearance of clindamycin.

Inducers of CYP3A4 and CYP3A5 may increase clearance of clindamycin. Patients should be observed for reduced treatment efficacy if clindamycin is used together with strong CYP3A4 inducers such as rifampicin.

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 medicines metabolized by these CYP enzymes are unlikely.

Immunosuppressive agents

Clindamycin may impact blood concentrations of ciclosporin and tacrolimus. Monitoring ciclosporin/tacrolimus serum levels during treatment with clindamycin is recommended.

4.6 Fertility, pregnancy and lactation

Pregnancy

In clinical studies in pregnant women, systemic administration of clindamycin during the 2nd and 3rd trimesters was not associated with an increased incidence of congenital abnormalities. There are no adequate, well-controlled studies in pregnant women during the first trimester of pregnancy. Clindamycin crosses the placenta in humans.

Clindamycin should only be used if absolutely necessary during pregnancy.

Breast-feeding

After systemic administration, clindamycin has been reported to appear in human breast milk ranging from < 0.5 to 3.8 μg/ml. Clindamycin can potentially have a negative effect on the intestinal flora of the breast-fed infant with symptoms such as diarrhoea or blood in the stool or rash. It is not recommended to use clindamycin during breastfeeding, and a decision must be made to either stop breast-feeding or choose another treatment option. The benefits of breast-feeding for the infant should be weighed against the mother’s clinical need for clindamycin.

Fertility

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

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 2 below lists the adverse reactions identified through clinical trial experience and post-marketing experience. Adverse reactions are ranked by MedDRA system organ class and frequency as follows: 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 the available data).

Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

The most frequent side effects are gastrointestinal, predominantly diarrhoea. Gastrointestinal side effects occur in approx. 8 % of patients.

Table 2 Adverse reactions

System Organ Class	Common	Uncommon	Rare	Very rare	Not known
Infections and infestations	Pseudomembranous colitis*#				*Clostridioides difficile* colitis*#, vaginal infection*
Blood and lymphatic system disorders	Eosinophilia	Granulocytopenia			Agranulocytosis*, neutropenia*, thrombocytopenia*, leucopenia*, thrombocytopenic purpura
Immune system disorders			Angioedema		Anaphylactic shock*, anaphylactoid reaction*#, anaphylactic reaction*, hypersensitivity*+
Nervous system disorders		Dysgeusia, neuromuscular blocking effect			Changes in smell
Cardiac disorders		Cardio-respiratory arrest§			
Vascular disorders	Thrombophlebitis ****	Hypotension§			

Gastrointestinal disorders	Inflammation of the oral mucosa, diarrhoea**	Abdominal pain, oesophagitis, nausea, vomiting		Dyspepsia	
Hepatobiliary disorders					Jaundice*
Skin and subcutaneous tissue disorders	Maculo-papular rash	Urticaria, erythema multiforme, pruritus			Toxic epidermal necrolysis (TEN)*#, Stevens-Johnson syndrome (SJS)*#, drug reaction/drug exanthem with eosinophilia and systemic symptoms (DRESS)*#, acute generalised exanthematous pustulosis (AGEP)*#, exfoliative dermatitis*, dermatitis bullous*, morbilliform rash*
Renal and urinary disorders					Acute kidney injury#
General disorders and administration site conditions	Induration at the injection site***	Pain at the injection site, sterile abscess at the injection site***			Irritation at the injection site*
Investigations	Liver function tests abnormal, serum transaminases increased				

* Adverse reactions identified from post-marketing experience.

** Often mild in nature and often resolve during or after discontinuation of treatment. These side effects depend on the method of administration and the dosage.

*** May occur locally after IM injection.

**** After IV administration.

\+ After a rapid IV injection, hypersensitivity reactions in the form of flushing or feeling of nausea may occur.

\# See section 4.4.

§ Cases of cardio-respiratory arrest and hypotension have been reported following too rapid IV administration.

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 the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms of overdose are nausea, vomiting and diarrhoea.

Haemodialysis and peritoneal dialysis are not effective in removing clindamycin from the serum.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antibacterials for systemic use, lincosamides,
ATC code: J01FF01

Mechanism of action
Clindamycin is a lincosamide antibiotic that inhibits bacterial protein synthesis. It binds to the 50S subunit of the bacterial ribosome, and affects both the synthesis and the translation process in ribosomes. Although clindamycin phosphate is inactive *in vitro*, rapid *in vivo* hydrolysis converts this substance to the antibacterially active clindamycin.
Clindamycin exhibits bacteriostatic activity *in vitro* at usual doses.

Pharmacokinetic/pharmacodynamic relationship
The efficacy is related to the area under the concentration-time curve of the unbound fraction of the agent that exceeds the minimum inhibitory concentration (MIC) of the pathogen (fAUC/MIC).

Mechanism(s) of 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 (MLS_B resistance). 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.
The majority of methicillin-resistant *S. aureus* (MRSA) shows the constitutive MLS_B type of resistance and is therefore resistant to clindamycin. Infections caused by macrolide-resistant staphylococci should not be treated with

clindamycin, also when *in vitro* susceptibility was proven, because therapy may lead to selection of mutants with constitutive MLS_B resistance.
Strains with constitutive MLS_B resistance show complete cross-resistance of clindamycin with lincomycin, macrolides (e.g. azithromycin, clarithromycin, erythromycin, roxithromycin, spiramycin) as well as streptogramin B.

Susceptibility testing breakpoints
MIC (minimum inhibitory concentration) interpretive criteria for susceptibility testing have been established by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) for clindamycin and are listed here: https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx

Prevalence of acquired resistance
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 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.

Commonly susceptible species

Aerobic gram-positive microorganisms
Staphylococcus aureus (methicillin-susceptible and methicillin-susceptible coagulase-negative staphylococci)
Streptococcus, groups A, B, C and G
Streptococcus pneumoniae (penicillin-susceptible isolates)
Streptococcus pyogenes
Streptococci of the viridans-group

Anaerobic gram-positive microorganisms
Clostridium perfringens
Peptostreptococcus spp. *(Finegoldia magna, Micromonas micros)*
Actinomyces israelii
Cutibacterium acnes
Peptoniphilus spp. [1]
Propionibacterium spp. [1]

Anaerobic gram-negative microorganisms
Fusobacterium spp. *(*excl. *F. varium)*
Prevotella spp.
Veillonella spp. [1]

Other microorganisms
Chlamydia trachomatis
Gardnerella vaginalis
Chlamydophila pneumoniae [1]

Mycoplasma hominis [1]

[1] *No updated data were available at release of tables. Primary literature, scientific standard literature, and therapeutic recommendations have been used to assume susceptibility.*

Species for which acquired resistance may be a problem

Aerobic gram-positive microorganisms
Staphylococcus aureus (methicillin-resistant)
Staphylococcus epidermidis
Staphylococcus haemolyticus
Staphylococcus hominis
Streptococcus agalactiae
Corynebacterium spp.

Aerobic gram-negative microorganisms
Moraxella catarrhalis

Anaerobic gram-positive microorganisms
Clostridioides difficile

Anaerobic gram-negative microorganisms
Bacteroides spp.

Inherently resistant organisms

Aerobic gram-positive microorganisms
Enterococcus spp.
Listeria monocytogenes

Aerobic gram-negative microorganisms
Escherichia coli
Haemophilus influenzae
Klebsiella spp.
Pseudomonas aeruginosa

Other microorganisms
Ureaplasma urealyticum
Mycoplasma pneumoniae

5.2 Pharmacokinetic properties

Absorption

After intramuscular injection of 600 mg clindamycin phosphate, peak serum levels of clindamycin ranging between 5 and 10 µg/ml are observed in a period of 1 to 4 hours after administration. After an intravenous infusion of 300 mg in 10 minutes and

600 mg in 20 minutes, peak serum levels at the end of the infusion are 7 µg/ml and 10 µg/ml, respectively.

Clindamycin serum levels can be maintained above the minimum inhibitory concentration *in vitro* for most susceptible microorganisms by administration of clindamycin phosphate every 8-12 hours in adults and every 6-8 hours in children over 3 years of age by intravenous infusion. A constant level is achieved after the third dose.

Distribution

The protein binding is between 40 % and 94 %. Clindamycin readily penetrates most body fluids and tissues (including bones) and is thus an alternative for hard-to-reach foci of infection such as soft tissue infections and acute and chronic osteomyelitis. Approximately 40 % (20-75 %) of the serum level are achieved in bone tissue, in breast milk 50-100 %, in synovial fluid 50 %, in sputum 30-75 %, in peritoneal fluid 50 %, in foetal blood 40 %, in pus 30 %, in the pleural fluid 50-90 %. However, clindamycin does not penetrate the cerebrospinal fluid, even in cases of meningitis.

After multiple doses, amniotic fluid concentrations were approximately 30 % of maternal blood concentrations.

Biotransformation

In vitro studies in human liver and intestinal microsomes indicated that clindamycin is predominantly oxidized by CYP3A4, with a minor contribution from CYP3A5, forming metabolites clindamycin sulfoxide and a minor metabolite, N-desmethylclindamycin.

Plasma half-life of clindamycin is 2.4 hours. In patients with renal insufficiency and moderate to severe hepatic insufficiency, the half-life is prolonged.

Elimination

After parenteral administration, approximately 15 % of the administered dose is excreted in the urine. Excretion is mainly through bile and faeces as biologically inactive metabolites.

Haemodialysis and peritoneal dialysis are not effective treatment methods for removing clindamycin from serum.

Linearity/non-linearity

Serum clindamycin concentrations increase linearly with increasing dose.

Specific populations

Obese paediatric patients 2 to < 18 years of age and obese adults 18 to 20 years of age

Pharmacokinetic studies in obese paediatric patients (2 to < 18 years) and obese adults aged 18 to 20 years show that the clearance and volume of distribution of clindamycin, normalized in total body weight, are comparable between obese and non-obese patients.

Elderly

Pharmacokinetic studies with older subjects (61-79 years) and younger adults (18-39 years) indicate that age alone does not change clindamycin's pharmacokinetics (clearance, elimination half-life, volume of distribution and AUC after IV administration of clindamycin).

Renal impairment

The serum half-life of clindamycin is slightly increased in patients with severe renal impairment (see section 4.2).

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, toxicity to reproduction and development.

Carcinogenicity

Long-term animal carcinogenicity studies have not been performed.

Mutagenicity

Genotoxic tests performed include a micronucleus test in rats and an Ames Salmonella Reversion test. Results from both tests were negative.

Reproductive toxicity

In experiments on embryo-foetal development in rats with oral dosing and experiments on embryo-foetal development in rats and rabbits with subcutaneous dosing, developmental toxicity was only observed at doses that resulted in maternal toxicity.

Animal reproduction studies are not always predictive of human response.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate

Sodium hydroxide (for pH adjustment)

Water for injections

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

The following medicinal products are physically incompatible with clindamycin phosphate: ampicillin, phenytoin sodium, barbiturates, aminophylline, calcium gluconate, magnesium sulphate, ceftriaxone sodium, ciprofloxacin, idarubicin hydrochloride and ranitidine hydrochloride.

6.3 Shelf life

18 months.

Shelf life after opening the ampoule: The product should be used immediately.

Shelf life after dilution

Chemical and physical in-use stability has been demonstrated for 48 hours at 25 °C and 2-8 °C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are responsibility of the user and would not normally be longer than 24 hours at 2-8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

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

Keep the ampoules in the outer carton in order to protect from light.

For storage conditions after first opening and dilution of the medicinal product, see section 6.3.

6.5 Nature and contents of container

2 ml or 4 ml of solution filled in colourless glass ampoules with one point cut.

Each pack contains 1, 5 or 10 ampoules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

For single use only. Discard any unused portion.

The medicinal product should be visually inspected prior to use. Do not use if there are any visible signs of deterioration (e.g. particles). Only clear solutions free from visible particles should be used.

May be diluted with:

- 9 mg/ml (0.9 %) sodium chloride solution for infusion
- 50 mg/ml (5 %) glucose solution for infusion

The concentration of clindamycin in the diluent should not exceed 18 mg/ml. See section 4.2 for further recommendations on dilution of the product before administration.

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

7 MARKETING AUTHORISATION HOLDER

AS KALCEKS

Krustpils iela 71E, Rīga, LV-1057, Latvia

8 MARKETING AUTHORISATION NUMBER(S)

PL 47015/0040

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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