Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Clindamycin 150 mg/ml solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution for injection/ concentrate for solution for infusion contains 150 mg clindamycin (as phosphate).

Each ampoule with 2 ml contains 300 mg clindamycin.
Each ampoule with 4 ml contains 600 mg clindamycin.
Each ampoule with 6 ml contains 900 mg clindamycin.

Excipients with known effect:
This medicinal product contains 9 mg benzyl alcohol and 8.5 mg sodium per ml. This sodium content is equivalent to 0.43% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection / concentrate for solution for infusion.
The medicinal product is a clear and colourless to slightly yellow coloured solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Clindamycin is indicated for the treatment of the following severe infections caused by clindamycin susceptible microorganisms (see section 5.1). In case of aerobic infections clindamycin constitutes an alternative treatment in case other antibacterial agents are inactive or contra-indicated (e.g. in case of allergy to penicillins). In case of anaerobic infections a treatment with clindamycin as first choice agent can be envisaged.

- Staphylococcal bone and joint infections such as osteomyelitis and septic arthritis
- Chronic sinusitis caused by anaerobic microorganisms
- Infections of the lower respiratory tract such as:
    - aspiration pneumonia, pulmonary abscess, necrotising pneumonia and empyema

In case of suspected polymicrobial pulmonary infections, an agent with adequate activity against GGram-negative bacteria should also be given in combination to cover possible Gram-negative bacteria.

- Intra-abdominal infections such as peritonitis and abdominal abscess where the treatment of choice is clindamycin associated with an antibiotic with good activity against aerobic Gram-negative bacteria.
- Pelvic and female genital infections such as PID, endometritis, perivaginal infections, tubo-ovarian abscesses, salpingitis, pelvic cellulites when simultaneously another antibiotic with good activity against aerobic Gram-negative bacteria is administered.
- Skin and soft tissue infections

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

4.2 Posology and method of administration

Posology

Adults and adolescents older than 12 years

- for the treatment of severe infections (such as intra-abdominal infections, female pelvic infections or other severe infections):

12 to 18 ml Clindamycin daily (corresponding to 1800 to 2700 mg clindamycin)
in 2 - 4 equal doses, generally in combination with an antibiotic with good activity against aerobic Gram-negative bacteria.

for the treatment of less complicated infections: 8 to 12 ml Clindamycin daily (corresponding to 1200 to 1800 mg clindamycin) administered in three or four equal doses.

Normally the maximum daily dose for adults and adolescents older than 12 years is18 ml Clindamycin (corresponding to 2700 mg clindamycin) in 2 to 4 equal doses. In life-threatening infections doses up to 4800 mg/day have been given.
Single intramuscular (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 medicinal product may be administered in the form of a single rapid infusion of the first dose followed by continuous intravenous (IV) infusion.
Paediatric Population
Children (over 1 month of ageup to 12 years):
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.
Older people:
The half-life, volume of distribution and clearance, and extent of absorption after administration of clindamycin phosphate are not altered by increased age. Analysis of data from clinical studies has not revealed any age-related increase in toxicity. Dosage requirements in older people should not be influenced, therefore, by age alone. See section 4.4 for other factors which should be taken into consideration.

Clindamycin
Patients with hepatic impairment
In patients with liver disease of moderate to severe degree, elimination half-life of clindamycin is prolonged. A reduction in dosage is generally not necessary if Clindamycin is administered every 8 hours. However, the plasma concentration of clindamycin should be monitored in patients with severe hepatic insufficiency. Depending on the results, this measure can make a reduction in dosage or an increase in the dose intervals necessary.
Patients with renal impairment:
In the presence of kidney diseases, elimination half-life is prolonged; however, a dosage reduction is not necessary in the event of mild to moderate impairment of renal function. Nevertheless, the plasma concentration should be monitored in patients with severe renal insufficiency or anuria. Depending on the results, this measure can make a reduction in dosage or an increase in the dose interval of 8 or even 12 hours necessary.
Dosage in the event of haemodialysis
Clindamycin cannot be removed by haemodialysis. Therefore, no additional dose is necessary before or after haemodialysis.
Duration of treatment
In case of proven or even suspected infections with ß-haemolytic streptococci the treatment with Clindamycin should be continued for at least 10 days.
Since this medicinal product contains benzyl alcohol it should not be used for more than 7 days in young children (less than 3 years old), unless longer duration of treatment is required (see section 4.4).
Method of administration
Clindamycin is administered by intramuscular injection or intravenous infusion.
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
For intramuscular administration Clindamycin should be used undiluted.
For instructions on dilution of the medicinal product before administration, see section 6.6.

4.3 Contraindications

Hypersensitivity to clindamycin or lincomycin (parallel allergy exists) or to any of the excipients listed in section 6.1.
Clindamycin

4.4 Special warnings and precautions for use

Clindamycin should only be used in the treatment of serious infections. In considering the use of Clindamycin, 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 Clindamycin. The disease is likely to follow a more severe course in older patients or patients who are debilitated.

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).

Caution should be exercised in patients with

- impaired hepatic and renal function (see section 4.2),
- disturbances in neuromuscular transmission (myasthenia gravis, Parkinson's disease, etc.) as well as
- a history of gastrointestinal disorders (e.g. earlier inflammations of the colon).
- atopic diseases.

Severe allergic reactions can occur even after the first application. In this event treatment with Clindamycin must be discontinued immediately and the standard emergency measures should be implemented.

Rapid intravenous injection may have a serious effect on the heart (see section 4.8) and must be avoided.

In infants under the age of one year and in long-term therapy (treatment for more than 10 days), the haemogram as well as hepatic and renal function should be monitored at regular intervals.

Long-term and repeated application of Clindamycin can lead to a superinfection and/or colonisation with resistant pathogens or yeasts on the skin and mucous membranes.

Acute kidney injury
Acute kidney injury, including acute renal failure, has been reported infrequently. Therefore, monitoring of renal function should be considered in patients receiving prolonged therapy, suffering from pre-existing renal dysfunction or taking concomitant nephrotoxic drugs (see section 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.
The development of *Clostridium difficile* associated diarrhoea (CDAD) has been reported with use of nearly all antibacterial agents, including clindamycin. It ranges from mild diarrhoea to fatal colitis.
Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *Clostridium difficile*.
Clostridium difficile produces toxins A and B which contribute to the development of CDAD and is a primary cause of 'antibiotic-associated colitis'.
Hypervirulent strains of *Clostridium difficile* are associated with increased morbidity and mortality since such infections may be resistant to antibiotic therapy and may require colectomy.
It is important to consider the diagnosis of CDAD in patients who present with diarrhoea subsequent to the administration of antibacterial agents.
In this case, a careful anamnesis has to be performed since a CDAD can occur up to two months after antibiotic therapy.
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 should not be used in case of acute infections of the respiratory tract, if these are caused by viruses.

Clindamycin is not suitable for the treatment of meningitis, for the concentration of antibiotic obtained in the liquor cerebrospinalis is too little.

This medicinal product contains benzyl alcohol, which may cause allergic reactions.
Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gasping syndrome") in young children. Therefore the medicinal product should not be given to newborn babies (up to 4 weeks old), unless recommended by the health care professional.
This medicinal product should not be used for more than a week in young children (less than 3 years old), unless advised by the health care professional.
Large amounts of benzyl alcohol can build-up in the body and may cause undesirable effects (called "metabolic acidosis"). This should be considered in pregnant and breast-feeding women as well as for patients with a liver and kidney disease.

4.5 Interaction with other medicinal products and other forms of interactions

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.

Wherever possible, Clindamycin should not be combined with erythromycin as, with regard to the antibacterial action, an antagonistic effect has been observed *in vitro*.

There is cross-resistance of pathogens towards clindamycin und lincomycin.

Due to its neuromuscular-blocking properties, Clindamycin can potentiate the effect of muscle relaxants. As a result of this, unexpected, life-threatening incidents may occur during surgery.

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 medicinal products metabolized by these CYP enzymes are unlikely.

4.6 Fertility, pregnancy and lactation

Pregnancy:
A large study on pregnant women, in which approx. 650 neonates exposed in the first trimester of pregnancy were examined, showed no increase in malformation rates. However, there are inadequate data regarding the safety of clindamycin in pregnancy.
Clindamycin crosses the placenta. It is assumed that a concentration with therapeutic effect can be reached in the fetus. When applied during pregnancy the benefits and risks must be carefully weighed against each other.

Lactation:
Clindamycin is distributed into human breast milk. Therefore, the possibility of sensitisation, diarrhoea and yeast colonisation of the mucous membranes in nurselings cannot be excluded. When applied during lactation the benefits and risks must be carefully weighed against each other.

Fertility
Animal studies revealed no effects on the fertility. There are no data about the influence of clindamycin on the fertility in humans.

4.7 Effects on ability to drive and use machines

Side effects like dizziness, sleepiness and headaches can constrict the ability to drive and use machines.

In isolated cases side effects (e.g. anaphylactic shock) have been observed (see 4.8.) which render patients incapable of participating actively in road traffic or operating machines and working without suitable precautions owing to unsteadiness.

4.8 Undesirable effects

a) Tabular summary of 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)
Not known (cannot be estimated form the available data)

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

System Organ Class	**Very common (≥ 1/10)**	**Common (≥ 1/100 to < 1/10)**	**Uncommon (≥ 1/1000 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		antibiotic-associated pseudomembranous colitis*#				*Clostridium difficile* colitis*, vaginal infection*
Blood and lymphatic system disorders		Agranulocytosis*, neutropenia, thrombocyte-penia*, leucopenia*, eosinophilia,				
Immune System disorders				drug fever, hypersensitivity reaction to benzyl alcohol ("gasping syndrome")	anaphylactic reaction*,#	anaphylactic shock*, anaphylactoid reaction, hypersensitivity*
Nervous system disorders			dysgeusia, neuromuscular-blocking effect			sleepiness, dizziness, headaches
Cardiac disorders			cardiorespiratory arrest§			
Vascular Disorders		thrombophlebitis	hypotension§			
Gastrointestinal disorders	diarrhoea, abdominal pain, vomiting, nausea					
Hepatobiliary disorders					transient hepatitis with cholestatic jaundice	jaundice*
Skin and subcutaneous tissue disorders		maculopapular exanthema, morbilliform exanthema*, urticaria		toxic epidermal necrolysis (TEN)*, Stevens Johnson syndrome	rash and formation of blisters (hypersensitivity reaction)	drug reaction with eosinophilia and systemic symptom

				(SJS)*, Lyell syndrome, angioedema, exfoliative dermatitis* bullous dermatitis*, erythema multiforme, pruritus, vaginitis		(DRESS)*, acute generalised exanthematous pustulosis (AGEP)*
Musculoskeletal and connective tissue disorders					Polyarthritis	
Renal and urinary disorders						Acute kidney injury[#]
General disorders and administrations site conditions			pain, injection site abscess			injection site irritation[*]
Investigations		Liver function test abnormal				

* ADR identified post-marketing
[#] 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 HPRA Pharmacovigilance. Website: www.hpra.ie.

4.9 Overdose

No overdose symptoms have yet been observed. Haemodialysis and peritoneal dialysis are ineffective. There is no known specific antidote. Clindamycin is administered via i.m. or i.v. route therefore gastric lavage is not useful.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:
Antibacterials for systemic use; Lincosamides

ATC code:
J01FF01

Mechanism of action
Clindamycin binds to the 50S subunit of the bacterial ribosome and inhibits protein synthesis.Clindamycin has a predominately bacteriostatic action.

Pharmacodynamic effects
The efficacy is basically dependent on the time period, in which the agent level is above the minimum inhibitory concentration (MIC) of the pathogen.

Mechanism(s) of resistance
Resistance to clindamycin can be due to the following mechanisms:
Resistance to staphylococci and streptococci is often based on methyl groups increasingly binding to the 23S rRNA (so-called constitutive MLS_B-resistance), whereby the binding affinity of clindamycin to the ribosome is highly reduced.

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.

Breakpoints

Common dilution series are used for clindamycin testing. Following minimum inhibitory concentrations for susceptible and resistant germs were defined:

EUCAST (Version 6.0, valid from 2016-01-01)

Clinical Breakpoints

Pathogen	Susceptible	Resistant
Staphylococcus[1]	≤ 0.25 mg/l	> 0.5 mg/l
Streptococcus A, B, C, G [1, 2]	≤ 0.5 mg/l	> 0.5 mg/l
S. pneumoniae [3]	≤ 0. 5 mg/l	> 0.5 mg/l
Viridans group *streptococci*[3]	≤ 0.5 mg/l	> 0.5 mg/l
Gram-negative anaerobes	≤ 4 mg/l	> 4 mg/l
Gram-positive anaerobes	≤ 4 mg/l	> 4 mg/l

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 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.

Commonly susceptible species
Aerobic Gram-positive microorganisms
Actinomyces israelii°
Staphylococcus aureus (Methicillin-sensitive)
Streptococcus pneumoniae
Streptococcus pyogenes
Streptococci of the „viridans"-group°^
Anaerobic microorganisms
Bacteroides spp.° (excl. *B. fragilis*)
Clostridium perfringens °
Peptoniphilus spp. °
Fusobacterium spp.°
Peptostreptococcus spp. °
Prevotella spp.
Propionibacterium spp. °
Veillonella spp.°
Other microorganisms
Chlamydia trachomatis°
Chlamydophila pneumoniae°
Gardnerella vaginalis°
Mycoplasma hominis°

Species for which acquired resistance may be a problem
Aerobic Gram-positive microorganisms
Staphylococcus aureus
Staphylococcus aureus (Methicillin-resistant)+
Staphylococcus epidermidis+

Staphylococcus haemolyticus
Staphylococcus hominis
Streptococcus agalactiae
Aerobic Gram-negative microorganisms
Moraxella catarrhalis[$]
Anaerobic microorganisms
Bacteroides fragilis

Inherently resistant organisms
Aerobic Gram-positive microorganisms
Enterococcus spp.
Listeria monocytogenes
Aerobic Gram-negative microorganisms
Escherichia coli
Haemophilus influenzae
Klebsiella spp.
Pseudomonas aeruginosa
Anaerobic microorganisms
Clostridium difficile
Other microorganisms
Mycoplasma pneumoniae
Ureaplasma urealyticum

° No updated data were available at release of tables. Primary literature, scientific standard literature and therapeutic recommendations assume susceptibility.
[$] Inherent susceptibility of most of the isolates shows intermediate resistance.
[+] At least on region shows resistance rates higher than 50%.
^ Collective name for a heterogeneous group of streptococci species. Resistance rate may vary according to the streptococci species present.

5.2 Pharmacokinetic properties

Absorption
A difference only has to be made between the clindamycin derivatives used up until the time of absorption and splitting of the esters. Afterwards clindamycin exists in the body as a free base (active form). The esters should be considered being prodrugs. Clindamycin phosphate is a water-soluble ester for parenteral application. After intramuscular injection of 300 mg, peak serum levels after 3 hours are approx. 6 microgram/ml, following intravenous application of 300 mg the mean serum concentrations after one hour are approx. 4 to 6 microgram/ml.

Distribution
The degree of binding of clindamycin to plasma proteins is concentration-dependent and lies within the therapeutic range of between40 and 94 %.

Clindamycin readily distributes into the tissues, passes through the placental barrier and distributes into breast milk. Even if the meninges are inflamed, diffusion into the subarachnoid space is inadequate. High concentrations are achieved in bone tissue,synovial fluid, peritoneal fluid, pleural fluid, expectorations and pus.The following concurrent serum concentrations of the active substance are reported: inbone tissue 40 % (20 – 75 %), in synovial fluid 50 %, in peritoneal fluid 50 %, in pleural fluid 50 – 90 %, in expectorations 30 – 75 % and in pus 30 %.

Metabolism
Clindamycin is metabolised primarily in the liver.
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 serum half-life of clindamycin is approx. 3 hours in adults and approx. 2 hours in children. In the presence of renal insufficiency and moderate to severe hepatic insufficiency, the half-life is prolonged.
Some metabolites are microbiologically active (N-demethyl and sulphoxide). Medicinal products that act as enzyme inducers in the liver shorten the mean retention time of clindamycin in the body.

Elimination
Clindamycin is eliminated via the faeces at 2/3 and via the urine at 1/3 of the dose. Less than 10% of the dose is excreted unchanged in the urine.
Clindamycin cannot be dialysed.

5.3 Preclinical safety data

Symptoms of intoxication are decreased activity of the animals and convulsions.
After repeated doses (i.m.) of clindamycin to dogs an increase of the SGOT and SGPT was reported and also a slight increase of the liver-weight without morphologic changes were documented. Long-term administration of clindamycin to dogs induced damages to the gastric mucosa and to the gall bladder.

Local reactions at the injection site (inflammations, haemorrhagias and tissue damage) were observed following intramuscular and subcutaneous application, however, the concentration of the solution applied far exceeded the maximum therapeutic concentration.

Mutagenicity and tumorigenic potential
In-vitro and in-vivo studies did not reveal any mutagenic potential of clindamycin. No long-term animal studies investigating the tumorigenic potential of clindamycin have been conducted.

Reproduction toxicity
Studies on clindamycin in rats and mice provided no evidence to indicate any fertility impairment or embryo/fetotoxic properties.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Disodium edetate
Sodium hydroxide (for pH-adjustment)
Water for injections

6.2 Incompatibilities

The following active substances are physically incompatible with Clindamycin: ampicillin, phenytoin sodium, barbiturates, aminophylline, calcium gluconate, ciprofloxacin, 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 medicinal products unstable at low pH.

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

6.3 Shelf life

Unopened:
18 months

After dilution:
Chemical and physical in-use stability has been demonstrated for 48 hours at 25 °C with sodium chloride 0.9 %, ringer lactate and glucose 5 % standard solutions.

From a microbiological point of view, once diluted, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 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.
For storage conditions after first opening and dilution of the medicinal product, see section 6.3.

6.5 Nature and contents of container

Type I clear glass ampoules.

2 ml:
Pack sizes: 5 or 10 ampoules

4 ml:
Pack sizes: 5 or 10 ampoules

6 ml:
Pack sizes: 5 or 10 ampoules

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Clindamycin **must** be diluted prior to IV administration (not exceeding 18 mg clindamycin per ml) and should be infused over at least 10 - 60 minutes (not exceeding 30 mg/min). It can never be injected as an IV bolus.

Dose:	Diluent:	Minimum infusion-time:
300 mg	50 ml	10 minutes
600 mg	50 ml	20 minutes
900 mg	50 -100 ml	30 minutes
1200 mg	100 ml	60 minutes

Clindamycin may be diluted with 0.9 % sodium chloride solution, 5 % glucose solution or Ringer's lactate.

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

For single use only.

The medicinal product is to be visually inspected prior to use and also after dilution. Do not use Clindamycin if you notice any particles or strong coloration of the solution.
Only clear solutions free of visible particles should be used.

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

7 MARKETING AUTHORISATION HOLDER

Fresenius Kabi Deutschland GmbH
Else-Kroener Strasse 1
Bad Homburg v.d.H 61352
Germany

8 MARKETING AUTHORISATION NUMBER

PA2059/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th May 2008.
Date of last renewal: 19th January 2013

10 DATE OF REVISION OF THE TEXT

October 2021