Summary of Product Characteristics

1. Name of the Medicinal Product

Proprietary name: CLINEP

International Non-proprietary Name (INN): Clindamycin Injection USP 600 mg/4ml (5ml)

Each ml contains:

Clindamycin Phosphate USP

Eq. to Clindamycin : 150 mg

Benzyl Alcohol USP : 1 % w/v

(As Preservative)

Water for Injection USP: Q.S.

2. Qualitative and Quantitative Composition

Each ml contains Clindamycin Phosphate USP Eq. to Clindamycin 150 mg, Benzyl Alcohol USP 1 % w/v (As Preservative), Water for Injection USP Q.S. For the full list of excipients, see section 6.1.

3. Pharmaceutical Form

Clear colourless solution.

4. Clinical Particulars

4.1 Therapeutic indications

Antibacterial Serious infections caused by susceptible Gram-positive organisms, staphylococci (both penicillinase- and non-penicillinase-producing), streptococci (except Streptococcus faecalis) and pneumococci. It is also indicated for the treatment of severe infections caused by susceptible anaerobic pathogens such as Bacteroides spp, Fusobacterium spp, Propionibacteriumspp, Peptostreptococcus spp. and microaerophilic streptococci. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Clindamycin does not penetrate the blood/brain barrier in therapeutically effective quantities

4.2 Posology and method of administration

Posology Adults:

Serious infections: 600mg-1.2g/day in two, three or four equal doses.

More severe infections: 1.2-2.7g/day in two, three or four equal doses.

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

For more serious infections, these doses may have to be increased. In life-threatening situations, doses as high as 4.8gdaily have been given intravenously to adults.

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

Treatment for infections caused by beta-haemolytic streptococci should be continued for at least 10 days to guard against subsequent rheumatic fever or glomerulonephritis.

Elderly:

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 elderly patients should not be influenced, therefore, by age alone.

Paediatric population (over 1 month of age):

Serious infections: 15-25mg/kg/day in three or four equal doses.

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

Method of administration:

Parenteral (IM or IV administration).

Clindamycin 150mg/ml Solution for Injection and Infusion should be used undiluted for IM administration.

Clindamycin 150mg/ml Solution for Injection and Infusion must be diluted prior to I.V. administration and should be infused over at least 10-60 minutes.

Dilution for IV use and IV infusion rates:

The concentration of clindamycin in diluent for infusion should not exceed 18mg per ml and Infusion Rates should not Exceed 30mg 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 ml to 100 ml	30 min
1200 mg	100 ml	40 min

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

Solution for injection is for single use only. Any unused product should be discarded.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Clindamycin 150mg/ml Solution for Injection and Infusion is contra-indicated in patients previously found to be sensitive to lincomycin.

4.4 Special warnings and precautions for use

Warnings

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 generalizedexanthematous 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.

Clindamycin 600mg/4ml Solution for Injection and Infusion should only be used in the treatment of serious infections. In considering the use of the product, 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.

Precautions

Caution should be used when prescribing Clindamycin 600mg/4ml Solution for Injection and Infusion to individuals with a history of gastro-intestinal disease, especially colitis.

Since Clindamycin 600mg/4ml Injection does not diffuse adequately into cerebrospinal fluid, the drug should not be used in the treatment of meningitis.

Prolonged administration of Clindamycin 600mg/4ml Solution for Injection and Infusion, as with any anti-infective, may result in super-infection due to organisms resistant to clindamycin.

Care should be observed in the use of Clindamycin 600mg/4ml Solution for Injection and Infusion in atopic individuals.

Clindamycin phosphate should not be injected intravenously undiluted as a bolus, but should be infused over at least 10-60 minutes.

This medicine contains less than 1 mmol sodium (23 mg) per 2 ml ampoule, that is to say essentially 'sodium-free'.

This medicinal product contains 26 mg sodium per 4 ml ampoule, equivalent to 1.3% of the WHO recommended maximum daily intake of 2 g sodium for an adult."

Usage in the new born and infants

When clindamycin is administered to new born and infants, appropriate monitoring of organ system functions is desirable.

Usage in meningitis

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

4.5 Interaction with other medicinal products and other forms of interaction

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.

Clindamycin is metabolised predominantly by CYP3A4, and to a lesser extent by CYP3A5, to the major metabolite clindamycin sulfoxide and minor metabolite N-desmethyl clindamycin. 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 metabolised by these CYP enzymes are unlikely.

4.6 Pregnancy and lactation

4.6.1 Fertility

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

4.6.2 Pregnancy

There was evidence of maternal toxicity and embryofetal toxicity in animal studies.

Clindamycin crosses the placenta in humans. After multiple doses, amniotic fluid concentrations were approximately30% of maternal blood concentrations.

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.

4.6.3 Lactation

Orally and parenterally administered clindamycin has been reported to appear in human breast milk in ranges from < 0.5to 3.8 µg/ml. Clindamycin has the potential to cause adverse effects on the breastfed infant's gastrointestinal flora such as diarrhoea or blood in the stool, or rash.

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

Immune system disorders Rare:

Immediate hypersensitivity reactions, sometimes severe including anaphylaxis. Anaphylaxis may be fatal. Hypersensitivity reactions were also observed in patients, who were sensitive towards other selective 5-HT_3 receptor antagonists.

Nervous system disorders Very common: Headache.

Uncommon:

There have been reports suggestive of involuntary movement disorders such as extrapyramidal reactions, e.g. oculogyric crisis/dystonic reactions and dyskinesia without definitive evidence of persistent clinical sequelae and seizures (e.g. epileptic spasms) have been observed although no known pharmacological mechanism can account for ondansetron causing these effects.

Rare: Dizziness during rapid intravenous administration.

Very rare: Depression.

Cardiac disorders

Uncommon:

Chest pain with or without ST segment depression, cardiac arrhythmias and bradycardia. Chest pain and cardiac arrhythmias may be fatal in individual cases.

Rare:

Transitory changes in the electrocardiogram, QTc prolongation (including Torsades de Pointes) Unknown:

Myocardial ischemia

Vascular disorders

Common: Sensations of flushing or warmth.

Uncommon: Hypotension.

Paediatric population

The adverse event profile in children and adolescents was comparable to that seen in adults.

Reporting of Undesirable effects

Healthcare professionals are requested to report any suspected adverse reactions to the Pharmacy and Poisons Board (PPB) via https://pv.pharmacyboardkenya.org

4.9 Overdose

Management:

In cases of over dosage no specific treatment is indicated.

The serum biological half-life of Clindamycin is 2.4 hours. Clindamycin cannot readily be removed from the blood by dialysis or peritoneal dialysis.

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

Pharmacotherapeutic group: Lincosamides, 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 clindamycin is predominantly bacteriostatic although high concentrations may be slowly bactericidal against sensitive strains. Although clindamycin phosphate is inactive in vitro, rapid in vivo hydrolysis converts this compound to the antibacterially active clindamycin.

5.2 Pharmacokinetic properties

Absorption

Following parenteral administration, the biologically inactive clindamycin phosphate is hydrolysed to clindamycin. When the equivalent of 300mg of clindamycin is injected intramuscularly, a mean peak plasma concentration of 6 microgram/ml is achieved within three hours; 600mg gives a peak concentration of 9 microgram/ml.

Distribution

Clindamycin is widely distributed in body fluids and tissues, including bone, 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. 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- desmethyl clindamycin.

Biotransformation

Clindamycin undergoes metabolism, to the active N-demethyl and sulphoxide metabolites and also some inactive metabolites.

Elimination

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.

5.3 Preclinical safety data

Impairment of fertility

Fertility studies in rats treated orally with up to 300 mg/kg/day (2-fold the human exposure based on mg/m2) revealed no effects on fertility or mating ability.

Pregnancy

In oral embryo-fetal development studies in rats and subcutaneous embryo-fetal development studies in rats and rabbits, embryo-fetal toxicity was observed at doses that produced maternal toxicity. In rats, maternal death occurred with an exposure ratio of approximately 1 relative to patient exposure. In rabbits, maternal toxicity, including abortions, occurred at exposure ratio of approximately 0.1. Embryo-fetal toxicity, including post-implantation loss and decreased viability, occurred in rabbits at an exposure ratio of 0.2.

Carcinogenesis

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

Mutagenesis

Geno toxicity tests performed included a rat micronucleus test and an Ames test. Both tests were negative.

6. Pharmaceutical Particulars

6.1 List of excipients

Clindamycin Phosphate

Eq.to Clindamycin	USP
Benzyl alcohol	USP
Di sodium E.D.T.A	BP
Sodium Metabisulphite	BP
Potassium Dihydrogen phosphate	BP
Sodium Hydroxide	BP

Water for injection USP

6.2 Incompatibilities

NA

6.3 Shelf life

36 Months

6.4 Special precaution for storage

Store at below 25°C. Protect from heat, light and moisture.

KEEP OUT OF REACH OF CHILDREN

6.5 Nature and contents of container 1×5 ml, Clear glass vial USP Type-1.

6.6 Special precautions for disposal and other handling No special requirements.

7. Marketing Authorization Holder and Manufacturing Site Addresses

Marketing Authorization Holder

LAVITA PHARMA PRIVATE LIMITED

Ahmedabad

Gujarat, India

Manufacturing Site Addresses

ARMEIN PHARMACEUTICALS PVT.LTD.

Kambhat-petlad road, Bamanva - 388580

Kambhat, Ananda

Gujarat, India.

8. Marketing Authorization Number

H2025/CTD12604/26522

9. Date of First Registration

21/11/2025

10. Date of revision of text

21/11/2025