Summary of Product Characteristics
CLINDA GPO

WARNINGS

Clindamycin can cause severe and possibly fatal colitis. Should be reserved for serious infections where less toxic antimicrobial agents are inappropriate. It should not be used in patients with nonbacterial infections such as most upper respiratory tract infections. Hypertoxin-producing strains of Clostridium difficile cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. C. difficile-associated diarrhea (CDAD) must be considered in all patients who present with diarrhea following antibiotic use. CDAD has been observed >2 months postantibiotic treatment. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be discontinued. Institute appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation as clinically indicated.

1. Name of the medicinal product

CLINDA GPO (150 and 300 mg)

2. Qualitative and quantitative composition

CLINDA GPO 150

Each capsule contains clindamycin hydrochloride equivalent to clindamycin 150 mg (INN: clindamycin)

CLINDA GPO 300

Each capsule contains clindamycin hydrochloride equivalent to clindamycin 300 mg (INN: clindamycin)

3. Pharmaceutical form

150 mg: An opaque, maroon/lavender, hard capsule No. 1 filled with white powder and imprinted with “GPO” on marron cap and “150” on lavender body with white ink.

300 mg: An opaque, purple, hard gelatin capsule No.0 , filled with white powder and imprinted with "GPO" on cap and "300" on body with white ink.

4. Clinical Particulars

4.1. Therapeutic indication

Clindamycin is used for the treatment of certain serious infections caused by susceptible aerobic gram-positive bacteria (staphylococci, streptococci, pneumococci) and for the treatment of certain serious infections caused by susceptible anaerobic bacteria. [1, Uses, p. 377]

- For treatment of serious respiratory tract infections (e.g., pneumonia, empyema, lung abscess), caused by susceptible S. aureus, S. pneumoniae, other streptococci, or anaerobes, pharyngitis and tonsilitis caused by *S. pyogenes* (group A ß-hemolytic streptococci; GAS), acute otitis media. [1, Uses, p. 377]
- For treatment of serious skin and skin structure infections caused by susceptible staphylococci, *S. pneumoniae*, *S. pyogenes* (group A ß-hemolytic streptococci; GAS), other streptococci, or anaerobes. [1, Uses, p. 377]
- For the treatment of babesiosis caused by *Babesia microti* or other *Babesia* in conjunction with oral quinine sulfate. [1, Uses, p. 378]
- Treatment of bone and joint infections, including acute hematogenous osteomyelitis caused by *Staphylococcus aureus* and as adjunctive therapy in the surgical treatment of chronic bone and joint infections caused by susceptible organisms. [2, Use, p. 560]
- Treatment of gynecologic infections, including endometritis, nongonococcal tubo-ovarian abscess, pelvic cellulitis, and postsurgical vaginal cuff infection caused by susceptible anaerobes. [2, Use, p. 560]

- Treatment of bacterial vaginosis. [1, Uses, p. 378]
- Treatment of intra-abdominal infections, including peritonitis and intra-abdominal abscess caused by susceptible anaerobic organisms. [2, Use, p. 560]
- Treatment of septicemia caused by *S. aureus*, streptococci (except *E. faecalis*), and susceptible anaerobes. [2, Use, p. 560]
- For the treatment of uncomplicated chloroquine-resistant *Plasmodium falciparum* malaria in conjunction with quinine sulfate. [1, Uses, p. 378]
- For the treatment of *Pneumocystis jirovecii* (formerly, *Pneumocystis carinii*) pneumonia (PCP) individuals with human immunodeficiency virus (HIV) infection. Clindamycin is used in conjunction with primaquine. [1, Uses, p. 379]
- For the treatment of toxoplasmosis caused by *Toxoplasma gondii* in HIV-infected adults and adolescents who are unable to tolerate sulfadiazine or who failed to respond to an initial regimen of pyrimethamine and sulfadiazine. Clindamycin is used in conjunction with pyrimethamine (and leucovorin). [1, Uses, p. 379]
- For prevention of α-hemolytic (viridans group) streptococcal bacterial endocarditis in penicillin-allergic adults and children undergoing certain dental or upper respiratory tract procedures who have cardiac conditions that put them at highest risk of adverse outcomes from endocarditis. [1, Uses, p. 380]

4.2. Posology and method of administration

CLINDA GPO can be administered without regard to food. [1, Dosage and administration, p. 381]

Infants and children: [1, Dosage and administration, p. 382]

When clindamycin capsules are used in pediatric patients able to swallow capsules, it is recommended that 8-16 mg/kg daily given

in 3 or 4 equally divided dose for the treatment of serious infections or 16-20 mg/kg daily given in 3 or 4 equally divided doses for more severe infections.

Adults:

The usual dosage is 150-300 mg every 6 hours for the treatment of serious infections or 300-450 mg every 6 hours for the treatment of more severe infections. [1, Dosage and administration, p. 382]

Acute otitis media [1, Dosage and administration, p. 382]

In children 6 months through 12 years of age, a dosage of 30-40 mg/kg daily given in 3 divided doses (with or without a third generation cephalosporin) is recommended.

Pharyngitis and tonsilitis [1, Dosage and administration, p. 382]

A dosage of 10 mg/kg 3 times daily (up to 900 mg daily) for 10 days for the treatment of pharyngitis and tonsilitis caused by *S. pyogenes* (group A ß-hemolytic streptococci: GAS).

Respiratory tract infections [1, Dosage and administration, p. 382]

For the treatment of healthcare-associated or community-acquired pneumonia (CAP) caused by susceptible methicillin-resistant *S. aureus* (MRSA): a dosage of 600 mg 3 times daily for 7-21 days is recommended.

For the treatment of CAP caused by susceptible gram-positive bacteria (e.g., *S. pneumoniae*, *S. pyogenes*, *S. aureus*) in children older than 3 months of age: a dosage of 30-40 mg/kg daily given in 3 or 4 divided doses.

Babesiosis [1, Dosage and administration, p. 382]

For the treatment of babesiosis caused by *Babesia microti* or other *Babesia* species in adults: a dosage of 600 mg orally every 8 hours in conjunction with oral quinine sulfate (650 mg every 6 or 8 hours) given for 7-10 days.

Bacterial vaginosis [1, Dosage and administration, p. 382]

A dosage of 300 mg twice daily for 7 days is recommended.

Uncomplicated malaria caused by chloroquine-resistant *Plasmodium falciparum* [1, Dosage and administration, p. 382]

A dosage of 20 mg/kg daily in 3 equally divided doses given for 7 days in conjunction with oral quinine sulfate (650 mg 3 times daily given for 7 days if acquired in Southeast Asia or for 3 days if acquired elsewhere) is recommended.

***Pneumocystis jirovecii* pneumonia** [1, Dosage and administration, p. 382]

A dosage of 450 mg every 6 hours or 600 mg every 8 hours for 21 days in conjunction with oral primaquine (30 mg once daily for 21 days) is recommended.

Toxoplasmosis caused by *Toxoplasma gondii* in HIV-infected adults and adolescents [1, Dosage and administration, p. 382-383]

A dosage of 600 mg every 6 hours in conjunction with oral pyrimethamine (200 mg loading dose followed by 50 mg once daily in those weighing less than 60 kg or 75 mg once daily for those weighing 60 kg or more) and oral leucovorin (10-25 mg once daily; may be increased to 50 mg once or twice daily). Treatment should be continued for at least 6 weeks.

For long-term suppressive therapy or chronic maintenance therapy, a dosage of 600 mg every 8 hours with pyrimethamine (25-50 mg once daily) and leucovorin (10-25 mg once daily).

Prevention of bacterial endocarditis [1, Dosage and administration, p. 383]

A single 600-mg dose for adults and a single 20-mg/kg dose for children 30-60 min before the procedure.

Skin and soft tissue infection [2, Dosing, p. 562]

Impetigo or ecthyma if MRSA is suspected or confirmed: 300 mg 4 times daily or 450 mg 3 times daily for 7 days

Nonpurulent cellulitis or erysipelas due to ß-hemolytic streptococci or *S. aureus* (including MRSA), empiric or pathogen-directed therapy: 300 mg 4 times daily or 450 mg 3 times daily.

Dosage in renal impairment [1, Dosage in renal and hepatic impairment, p. 384]

Dosage adjustment is not necessary in patients with renal impairment.

Dosage in hepatic impairment [1, Dosage in renal and hepatic impairment, p. 384]

Dosage adjustment is not necessary in patients with hepatic impairment. However, because the plasma half-life of clindamycin may be prolonged, hepatic function should be monitored if the drug is used in those with severe hepatic impairment.

In patients with moderate or severe liver disease, half-life is prolonged; however, when administered on an every-8-hour schedule, accumulation should rarely occur. In severe liver disease, use caution and monitor liver enzymes periodically during therapy. [2, Hepatic impairment, p. 563]

4.3. Contraindication [2, Contraindications, p. 560]

CLINDA GPO is contraindicated in patients with hypersensitivity to clindamycin, lincomycin, or any component of the formulation.

4.4. Special warning and precautions for use

Clindamycin can cause severe and possibly fatal colitis. Should be reserved for serious infections where less toxic antimicrobial agents are inappropriate. It should not be used in patients with nonbacterial infections such as most upper respiratory tract infections. Hypertoxin-producing strains of *Clostridium difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. *C. difficile*-associated diarrhea (CDAD) must be considered in all patients who present with diarrhea following antibiotic use. CDAD has been observed >2 months postantibiotic treatment. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Institute appropriate fluid and electrolyte

management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation as clinically indicated. [2, Warnings/Precautions, p. 560]

- Patients should be advised that diarrhea is a common problem caused by anti-infectives and usually ends when the drug is discontinued; however, it is important to contact a clinician if watery and bloody stools (with or without stomach cramps and fever) occur during or as late as 2 months or longer after the last dose. Clindamycin should always be discontinued if clinically important diarrhea occurs. The drug should be used with caution in patients with a history of gastrointestinal disease, particularly colitis. [1, Precautions and contraindications, p. 385]
- As with other anti-infectives, use of clindamycin may result in overgrowth of non-susceptible organisms, especially yeasts. If superinfection occurs, appropriate therapy should be institute. [1, Precautions and contraindications, p. 385]
- Severe hypersensitivity reactions, including severe skin reactions (e.g., drug reaction with eosinophilia and systemic symptoms [DRESS], Stevens Johnson syndrome [SJS], and toxic epidermal necrolysis [TEN]), some fatal, and anaphylactic reactions, including anaphylactic shock, have been reported. Permanently discontinue treatment and institute appropriate therapy if these reactions occur. [2, Warnings/Precautions, p. 560]
- Because clindamycin does not distribute adequately into the central nervous system (CNS), the drug should not be used for the treatment of CNS infections. [1, Precautions and contraindications, p. 385]
- During prolonged clindamycin therapy, liver and renal function tests and blood cell counts should be performed periodically. [1, Precautions and contraindications, p. 385]
- If clindamycin is used in patients with hepatic impairment, dosage adjustments may not be necessary; however, liver enzymes

should be monitored periodically when the drug is used in those with severe hepatic impairment. [1, Precautions and contraindications, p. 385]

Pediatrics [1, Pediatrics precautions, p. 385]

When clindamycin is used in pediatric patients (birth to 16 years of age), organ system functions should be monitored

Geriatrics [1, Geriatrics precautions, p. 385]

Clinical studies of clindamycin did not include sufficient numbers of patients 65 years of age or older to determine whether geriatric patients respond differently than younger patients. Clinical experience indicates that *C. difficile*-associated diarrhea and colitis seen in association with most anti-infectives may occur more frequently and be more severe in patients older than 60 years of age. Therefore, geriatric patients receiving clindamycin should be carefully monitored for the development of diarrhea (e.g., changes in bowel frequency).

Dosage adjustments are not usually necessary if clindamycin is used in geriatric patients with normal hepatic function and normal (age-adjusted) renal function.

4.5. Interactions with other medicinal products and other forms of interactions

Drug affecting or metabolized by hepatic microsomal enzymes [1, Drug interactions, p. 386]

Clindamycin is a moderate inhibitor of cytochrome P-450 (CYP) isoenzyme 3A4 and does not inhibit CYP1A2, 2C9, 2C19, 2E1, or 2D6.

Clindamycin is a substrate of CYP3A4 and, to a lesser extent, CYP3A5. Concomitant

use with CYP3A4 or 3A5 inhibitors may result in increased plasma concentrations of clindamycin, and concomitant use with CYP3A4 or 3A5 inducers may result in decreased plasma concentrations of clindamycin. If clindamycin is used concomitantly with a potent CYP3A4 inhibitor, the patient should be monitored for adverse

effects. If clindamycin is used concomitantly with a potent CYP3A4 inducer (e.g., rifampin), the patient should be monitored for loss of clindamycin effectiveness.

Neuromuscular blocking agents [1, Drug interactions, p. 386]

Clindamycin has been shown to have neuromuscular blocking properties that may enhance the neuromuscular blocking action of other agents (e.g., ether, tubocurarine, pancuronium). Clindamycin should be used with caution in patients receiving such agents, and such patients should be observed for prolongation of neuromuscular blockade.

Vitamin K antagonists [3, Interaction with other medicinal products and other forms of interaction, p. 2]

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.

Avoid concomitant use [2, Drug interactions, p. 561]

Concomitant use of clindamycin with any of the following should be avoided: BCG (intravesical), cholera vaccine, mecamylamine.

Vaccines [2, Drug interactions, p. 561]

Clindamycin may decrease the levels/effects of BCG (intravesical), BCG vaccine (immunization), cholera vaccine, typhoid vaccine.

Miscellaneous [2, Drug interactions, p. 561]

Clindamycin may decrease the levels/effects of Lactobacillus and estriol, sodium picosulfate. Kaolin may decrease the levels/effects of clindamycin.

4.6. Pregnancy and lactation

Pregnancy [1, Pregnancy, p. 385]

US Pregnancy category: Data is not available.

Reproduction studies in rats and mice using oral or parenteral dosages of clindamycin up to 600 mg/kg daily (3.2 and 1.6 times, respectively, the maximum recommended human oral dosage or 2.1 and 1.1 times, respectively, the maximum recommended human parenteral dosage on a mg/m^2 basis) have not revealed evidence of teratogenicity.

In clinical trials that included pregnant women, systemic clindamycin administered during the second and third trimesters was not associated with an increased frequency of congenital abnormalities. There are no adequate and well-controlled studies to date using clindamycin in pregnant women during the first trimester of pregnancy. Because animal reproduction studies are not always predictive of human response, clindamycin should be used during pregnancy only when clearly needed.

Lactation [1, Lactation, p. 385]

Clindamycin is distributed into milk and has the potential to cause adverse effects on the GI flora of breast-fed infants. Use of clindamycin in the mother is not a reason to discontinue breast-feeding; however, it may be preferable to use an alternate anti-infective. If clindamycin is used in a breast-feeding mother, the infant should be monitored for possible adverse effects on GI flora, including diarrhea and candidiasis (thrush, diaper rash) or, rarely, blood in the stool indicating possible antibiotic-associated colitis. The benefits of breast-feeding and the importance of clindamycin to the woman should be considered along with potential adverse-effects on the breast-fed child from the drug or from the underlying maternal condition.

4.7. Effects on ability to drive and use machine [3, 4.7 Effects on ability to drive and use machines, p. 3]

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

4.8. Undesirable effects [3, 4.8 Undesirable effects, p. 3-4]

Common adverse reactions
Infections and infestations: Pseudomembranous colitis
Gastrointestinal disorders: Diarrhea, abdominal pain
Investigations: Liver function test abnormal
Uncommon adverse reactions
Gastrointestinal disorders: Vomiting, nausea
Skin and subcutaneous tissue disorders: Rash, maculopapular, urticaria
Other adverse reactions (not known frequency, cannot be estimated from available data)
Infections and infestations: *C. 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
Gastrointestinal disorders: Esophageal ulcer, esophagitis
Hepatobiliary disorders: Jaundice
Skin and subcutaneous tissue disorders: Toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP), angioedema, dermatitis exfoliative, dermatitis bullous, erythema multiforme, pruritus, rash morbilliform
Renal and urinary disorders: Acute kidney injury

4.9. Overdose

Convulsions, depression, and death have been reported in mice receiving IV clindamycin doses of 855 mg/kg; death has been reported in rats receiving oral or subcutaneous clindamycin doses of 2.6 mg/kg. [1, Acute toxicity, p. 386]

In cases of overdosage no specific treatment is indicated. The serum biological half-life of clindamycin is 2.4 hours. [3, 4.9

Overdose, p. 4] Clindamycin is not removed by hemodialysis or peritoneal dialysis. [1, Acute toxicity, p. 386] If an allergic adverse reaction occurs, therapy should be with the usual emergency treatments, including corticosteroids, adrenaline, and antihistamines. [3, 4.9 Overdose, p. 4]

5. Pharmacological properties

5.1. Pharmacodynamic properties

Mechanism of action [1, Mechanism of action, p. 386]

Clindamycin usually is bacteriostatic in action, but may be bactericidal depending on the concentration of the drug attained at the site of infection and the susceptibility of the infecting organism.

Clindamycin inhibits protein synthesis in susceptible bacteria by binding to the 23S RNA of the 50S ribosomal subunits; the primary effect is inhibition of peptide bond formation. The site of action appears to be the same as that of erythromycin, chloramphenicol, and lincomycin.

Breakpoints [3, 5.1 Pharmacodynamic properties, p. 4-5]

The minimum inhibitory concentrations (MIC) breakpoints are as follows:

EUCAST

Staphylococci: sensitive ≤ 0.25 resistant > 0.5

Streptococci ABCG and pneumoniae: sensitive ≤ 0.5 resistant > 0.5

Gram positive anaerobes: sensitive ≤ 4 resistant > 4

Gram negative anaerobes: ≤ 4 resistant > 4

PK/PD relationship [3, 5.1 Pharmacodynamic properties, p. 5]

Efficacy is related to the ratio of the area of the concentration-time curve of unbound antibiotic to the MIC for the pathogen (fAUC/MIC).

Spectrum [1, Spectrum, p. 386]

Clindamycin is active in vitro against many gram-positive aerobic and anaerobic bacteria and some gram-negative anaerobic

bacteria. Clindamycin generally is inactive against most gram-negative aerobic bacteria.

Clindamycin is active in vitro against the following strains;

Staphylococcus aureus (methicillin-susceptible strains)
S. epidermidis (methicillin-susceptible strains)
Streptococcus pneumoniae (penicillin-susceptible strains)
S. pyogenes (group A ß-hemolytic streptococci; GAS)
S. agalactiae (group B streptococci; GBS)
S. anginosus
S. mitis
S. oralis

Clindamycin is active in vitro against some anaerobic and microaerophilic organisms including;

Actinomyces israelii
Clostridium clostridioforme
C. perfringens
Eggerthella lenta (previously known as *Eubacterium lentum*)
Finegoldia anaerobius
Finegoldia magna
Fusobacterium necrophorum
F. nucleatum
Micromonas micros
Mobiluncus
Prevotella (*P. disiens, P. intermedia, P. melaninogenica, P. vivia*)
Porphyromonas
Propionibacterium acnes
Gardnerella vaginalis

Clindamycin has in vitro activity against Toxoplasma gondii. The drug has been reported to have some activity against *Plasmodium falciparum* in vitro.

Clindamycin is inactive against;

Enterococcus faecalis
E. faecium
Enterobacteriaceae
Pseudomonas
Acinetobacter
Most strains of *Haemophilus influenzae* and *Neisseria*
Enterococci [3, 5.1 Pharmacodynamic properties, p. 5]
Clostridia spp [3, 5.1 Pharmacodynamic properties, p. 5]

Resistance [1, Resistance, p. 386]

Clindamycin resistance has been reported in clinical isolates of *S. aureus*, especially methicillin-resistant *S. aureus* (MRSA; also known as oxacillin-resistant *S. aureus* or ORSA), *S. agalactiae* (group B streptococci, GBS) and *Bacteroides fragilis*.

Complete cross-resistance occurs between clindamycin and lincomycin. Because of overlapping binding sites, partial cross-resistance has been reported between clindamycin and macrolides (e.g., erythromycin) and streptogramin B. In vitro, bacteria resistant to erythromycin and susceptible to clindamycin may exhibit a dissociated type of resistance to clindamycin during susceptibility testing if erythromycin is also present. This phenomenon may be the result of competition between erythromycin and clindamycin for the ribosomal binding site.

5.2. Pharmacokinetic properties [1, Pharmacokinetics, p. 387]

Absorption

Following oral administration of clindamycin hydrochloride, approximately 90% of the dose is rapidly absorbed from the GI tract. Following oral administration of a single 150-mg dose of clindamycin hydrochloride to healthy fasting adults, peak serum concentrations of clindamycin average 1.9-3.9 mcg/mL and are attained within 45-60 minutes; serum concentrations of clindamycin average 1.5 mcg/mL at 3 hours and 0.7 mcg/mL at 6 hours. Serum

concentrations of clindamycin appear to be predictable, increasing linearly with increased doses.

Clindamycin is not inactivated by gastric acidity. Administration of clindamycin hydrochloride capsules with food does not appreciably affect absorption or serum concentrations of the drug. Accumulation in plasma does not occur following multiple oral doses, including in neonates and infants up to 6 months of age.

Distribution

Clindamycin is widely distributed into body tissues and fluids, including saliva, ascites fluid, peritoneal fluid, pleural fluid, synovial fluid, bone, and bile. The concentration of clindamycin in synovial fluid and bone is reported to be 60-80% of concurrent serum concentrations of the drug; the degree of penetration does not appear to be affected by joint inflammation. Clinically important concentrations of clindamycin are not attained in CSF even in the presence of inflamed meninges.

Clindamycin readily crosses the placenta, and cord blood concentrations of the drug have been reported to be up to 50% of concurrent maternal blood concentrations.

Clindamycin is distributed into milk. Breast milk concentrations of 0.7-3.8 mcg/mL have been reported following clindamycin dosage of 150 mg orally. In one study in women who received oral clindamycin in a dosage of 150 mg 3 times daily, breast milk concentrations of the drug ranged from less than 0.5 to 3.1 mcg/mL.

At a concentration of 1 mcg/mL, clindamycin is approximately 93% bound to serum proteins.

Metabolism

Clindamycin is partially metabolized to bioactive and inactive metabolites. Clindamycin is predominantly metabolized by cytochrome P-450 (CYP) isoenzyme 3A4 and, to a lesser extent, by CYP3A5 to the major bioactive metabolite clindamycin sulfoxide and minor metabolite *N*-desmethylclindamycin.

Excretion

The serum half-life of clindamycin is 2-3 hours in adults and children. In neonates, the serum half-life of clindamycin depends on gestational and chronologic age and body weight. Half-life of the drug reportedly averages 8.7 or 3.6 hours in premature or full-term neonates, respectively, and about 3 hours in infants 4 weeks to 1 year of age; serum half-life was longer in infants weighing less than 3.5 kg than in heavier infants.

Following oral administration of clindamycin hydrochloride, elimination half-life increased to approximately 4 hours (range: 3.4-5.1 hours) in geriatric patients compared with 3.2 hours (range: 2.1-4.2 hours) in younger adults.

Clindamycin sulfoxide and *N*-desmethylclindamycin are excreted in urine, bile, and feces. Approximately 10% of an oral dose of clindamycin is excreted in urine and 3.6% is excreted in feces as active drug and metabolites; the remainder is excreted as inactive metabolites.

Renal and hepatic function impairments

The serum half-life of clindamycin is increased slightly in patients with markedly reduced renal or hepatic function.

5.3. Preclinical safety data

Mutagenicity and carcinogenicity [1, Mutagenicity and carcinogenicity, p. 385]

Clindamycin was not mutagenic in a rat micronucleus test or the Ames Salmonella reversion test.

Long-term studies in animals have not been performed to date to evaluate the carcinogenic potential of clindamycin.

Fertility [1, Pregnancy, fertility and lactation, p. 385]

Fertility studies in rats treated with oral clindamycin doses up to 300 mg/kg daily (about 1.1- 1.6 times the maximum recommended human dose on a mg/m^2 basis) have not revealed evidence of impaired fertility or mating ability.

6. Pharmaceutical Particulars

6.1. List of excipients

Lactose anhydrous, Pregelatinized Starch, Sodium Starch Glycolate, Magnesium Stearate, Talcum

6.2. Incompatibilities

Data is not available.

6.3. Shelf life

24 months

6.4. Special precautions for storage

Store below 30°C

6.5. Nature and contents of container

Box of 1x10 Capsules

7. Marketing Authorization Holder

Main Office: 75/1 Rama VI., Ratchathewi, Bangkok, Thailand

Manufacturer: 138 Moo 4, Rangsit-Nakhonnayok Rd., Bueng Sanan, Thanyaburi, Pathumthani, Thailand

8. Marketing Authorization Numbers

9. Date of authorization

10. Date of revision of the text

April 2022

References

1. *Clindamycin*, AHFS class: LINCOMYCINS [8:12.28.20] in AHFS Drug information, G.K. McEvoy, et al., Editors. 2021, American Society of Health-System Pharmacists: Maryland. p. 377-388.
2. *Clindamycin*, in Drug information Handbook, C.F. Lacy, et al., Editor30th ed., 2021, Lexi-Comp Inc.: Hudson. p. 560-564.

3. *Dalacin C Capsules 150 mg*, in *Summary of Product Characteristics*, Pfizer Limited, Kent, NJ, USA. [Revised September 2021]. Available from: https://www.medicines.org.uk/emc/product/1210/smpc.