SUMMARY OF PRODUCT CHARACTERISTICS
CLINDAZEN 150 (Clindamycin Hydrochloride Capsules USP 150 mg)

1. NAME OF THE MEDICINAL PRODUCT

CLINDAZEN 150 (Clindamycin Hydrochloride Capsules USP 150 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard gelatine capsule contains clindamycin hydrochloride equivalent to clindamycin 150 mg.

Excipients with known effect:

Each capsule contains 26.0 mg lactose monohydrate. For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard gelatine capsule.

Light blue opaque cap and light blue opaque body, size '2' hard gelatine capsule containing white powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Clindamycin is indicated for the treatment of serious infections caused by susceptible anaerobic bacteria, including intra-abdominal infections and skin and soft tissue infections. As needed, clindamycin should be administered in conjunction with another antibacterial agent active against gram-negative aerobic bacteria. Clindamycin is also indicated for: tonsillitis; dental infections.

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

4.2 Posology and method of administration

Adults

150–450 mg every 6 hours, depending on the severity of the infection.

Elderly

Dosage requirements in elderly patients should not be influenced by age alone.

Paediatric population

3–6 mg/kg every 6 hours depending on severity (not to exceed the adult dose). Clindamycin should be dosed based on total body weight regardless of obesity. Clindamycin capsules are not suitable for children unable to swallow them whole; an alternative formulation should be used in such cases.

Renal impairment

No dose adjustment is necessary in mild to moderate renal impairment. In severe renal impairment or anuria, plasma concentrations should be monitored; a reduction in dosage or an increase in dose interval (8 or even 12 hours) may be necessary.

Hepatic impairment

In moderate to severe hepatic impairment, elimination half-life of clindamycin is prolonged. A reduction in dosage is generally not necessary if clindamycin is administered every 8 hours. Plasma concentration of clindamycin should be monitored in severe hepatic impairment.

Method of administration

Oral. Capsules should always be swallowed whole and washed down with a full glass of water while in an upright position. Absorption is not appreciably modified by the presence of food.

4.3 Contraindications

- Hypersensitivity to clindamycin, lincomycin or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Hypersensitivity and severe skin reactions

Severe hypersensitivity reactions, including DRESS, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and acute generalised exanthematous pustulosis (AGEP), have been reported with clindamycin therapy. If a hypersensitivity or severe skin reaction occurs, clindamycin should be discontinued and appropriate therapy initiated.

Clostridium difficile-associated diarrhoea (CDAD)

Clindamycin should only be used in the treatment of serious infections. Cases of colitis have been reported during, or even 2–3 weeks following, clindamycin administration. CDAD has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhoea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon, leading to overgrowth of C. difficile, which produces toxins A and B contributing to CDAD development. Hypertoxin-producing strains cause increased morbidity and mortality and may be refractory to antimicrobial therapy, requiring colectomy. CDAD must be considered in all patients presenting with diarrhoea following antibiotic use, including up to 2 months after administration.

The appearance of marked diarrhoea should be regarded as an indication to immediately discontinue clindamycin. In severe cases, treatment with oral vancomycin (125–500 mg four times daily for 7–10 days) or fidaxomicin should be considered, according to local guidelines.

CNS penetration

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

Laboratory monitoring

Liver and renal function tests should be carried out during prolonged therapy. Close monitoring is also recommended in patients with renal or hepatic insufficiency and in neonates and infants.

Neuromuscular blocking

Clindamycin has neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. Use with caution in patients receiving such agents.

Acute kidney injury

Acute kidney injury, including acute renal failure, has been reported infrequently. In patients with pre-existing renal dysfunction or taking concomitant nephrotoxic drugs, monitoring of renal function should be considered.

Lactose content

This product contains 26.0 mg lactose per capsule. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Superinfection

Prolonged administration of clindamycin may result in superinfection due to organisms resistant to clindamycin.

4.5 Interaction with other medicinal products and other forms of interaction

Neuromuscular blocking agents:

Clindamycin may enhance the action of other neuromuscular blocking agents; use with caution.

Erythromycin:

Antagonism has been demonstrated in vitro; these two drugs should not be administered concurrently.

Vitamin K antagonists (warfarin, acenocoumarol, fluindione):

Increased coagulation tests (PT/INR) and/or bleeding have been reported. Coagulation tests should be frequently monitored in patients treated with vitamin K antagonists.

CYP3A4 and CYP3A5 inhibitors:

Clindamycin is metabolised predominantly by CYP3A4, and to a lesser extent by CYP3A5. Inhibitors of these isoenzymes may reduce clindamycin clearance and increase exposure. In the presence of strong CYP3A4 inducers (e.g. rifampicin), monitor for loss of effectiveness.

Note: In vitro studies indicate that clindamycin does not inhibit CYP1A2, CYP2C9, CYP2C19, CYP2E1 or CYP2D6, and only moderately inhibits CYP3A4; clinically important interactions through these pathways are unlikely.

4.6 Fertility, pregnancy and lactation

Pregnancy

Clindamycin crosses the placenta; amniotic fluid concentrations were approximately 30% of maternal blood concentrations after multiple doses. In clinical trials with pregnant women, systemic administration 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 during the first trimester. Clindamycin should be used in pregnancy only if clearly needed.

Breast-feeding
Clindamycin is excreted in breast milk (0.5–3.8 µg/mL). It has the potential to cause adverse effects on the breast-fed infant's gastrointestinal flora (diarrhoea or blood in stool) or rash. If clindamycin is required by a nursing mother, it is not a reason to discontinue breast-feeding; however, an alternate drug may be preferred. The benefits of breast-feeding should be considered along with the mother's clinical need for clindamycin and potential adverse effects on the child.

Fertility
In animal studies, clindamycin had no effect on fertility or mating ability.

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

4.8 Undesirable effects

System Organ Class	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Not known
Infections and infestations	Pseudomembranous colitis*		Clostridium difficile colitis*#, vaginal infection*
Blood and lymphatic			Agranulocytosis*, neutropenia*, thrombocytopenia*, leucopenia*, eosinophilia
Immune system			Anaphylactic shock*, anaphylactoid reaction*, anaphylactic reaction*, hypersensitivity*
Nervous system			Dysgeusia
Gastrointestinal	Diarrhoea, abdominal pain	Vomiting, nausea	Oesophageal ulcer*, oesophagitis*
Hepatobiliary			Jaundice*
Renal and urinary			Acute kidney injury
Skin and subcutaneous tissue			TEN*, SJS*, DRESS*, AGEP*, angioedema*, exfoliative dermatitis*, bullous dermatitis*, erythema multiforme*, pruritus, morbilliform rash*
Investigations	Liver function test abnormal		

** ADRs identified post-marketing.*

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 National Regulatory Authority.

4.9 Overdose
No specific treatment is indicated in cases of overdosage. The biological half-life of clindamycin is approximately 2.4 hours. Clindamycin cannot readily be removed from the blood by haemodialysis or peritoneal dialysis. If an allergic adverse reaction occurs, treat with usual emergency treatments including corticosteroids, adrenaline and antihistamines.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Lincosamides. ATC code: J01FF01.

Clindamycin is a lincosamide antibiotic with a primarily bacteriostatic action against gram-positive aerobes and a wide range of anaerobic bacteria. It binds to the 50S subunit of the bacterial ribosome similarly to macrolides, inhibiting the early stages of protein synthesis. At high concentrations, it may be slowly bactericidal against sensitive strains. Resistance usually occurs via macrolide-lincosamide-streptogramin B (MLSB) type resistance.

Susceptible organisms include: Staphylococcus aureus, S. epidermidis, Streptococcus pneumoniae, S. pyogenes, S. viridans; anaerobes including Bacteroides fragilis group, Clostridium perfringens, Fusobacterium spp., Peptococcus spp., Peptostreptococcus spp. and others. Resistant organisms include Clostridia spp., Enterococci and Enterobacteriaceae. Note: Up to 50% of methicillin-susceptible S. aureus and >90% of MRSA are resistant to clindamycin.

5.2 Pharmacokinetic properties

Absorption

After oral administration, clindamycin is rapidly absorbed (>90%). Absorption is not affected by food. Peak plasma concentration achieved within approximately 45 minutes. Bioavailability is non-linear and decreases with increasing doses; absolute bioavailability following a 600 mg dose is approximately 53%.

Distribution

Widely distributed in body fluids and tissues. Diffuses across the placenta but not the healthy blood-brain barrier. 68–93% bound to plasma proteins. Intracellular concentrations are 10–50-fold higher than extracellular concentrations due to lipophilic properties.

Biotransformation

Metabolised in the liver to the active N-demethyl and sulphoxide metabolites, and some inactive metabolites.

Elimination

Half-life approximately 2.5 hours in children and approximately 3 hours in adults. Excreted as biologically active and inactive metabolites in faeces, urine and bile. Faecal excretion is predominant. Approximately 10% is excreted in urine as active drug.

Special populations

Elderly: No change in half-life, volume of distribution, clearance or extent of absorption with increasing age. Renal impairment: Elimination half-life is prolonged; dose reduction not generally necessary in mild to moderate impairment. Hepatic impairment: Half-life prolonged in moderate to severe impairment; dose reduction not normally necessary when dosing every 8 hours. Obese paediatric and adult patients: Clindamycin clearance and volume of distribution normalised by total body weight are comparable regardless of obesity.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on studies of repeat dose toxicity, reproductive toxicity or genotoxicity. Carcinogenicity studies have not been conducted. In dogs, repeated high oral doses produced ulceration of the gastric and gall bladder mucosa.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate (excipient with known effect — 26.0 mg per capsule), maize starch, magnesium stearate, purified talc, colloidal anhydrous silica. Capsule shell: light blue opaque cap and light blue opaque body, size '2' hard gelatine capsules.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C. Protect from light. Keep out of the reach and sight of children.

6.5 Nature and contents of container

1 ALU-ALU blister of 10 capsules; 10 such blisters packed in a printed carton with package insert. Pack size: 100 capsules.

6.6 Special precautions for disposal and other handling

No special requirements. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

ZAIN PHARMA LTD.

Plot No. 209/13741, Colchester Park,

Go-Down No. 1, 2, 3, Off Mombasa Road,

Behind Nice and Lovely House,

P.O. Box: 100167-00101, Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2026/CTD12271/26748

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

17.12.2025

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