LINCOCIN® capsules, syrup, injection
(Lincomycin)

1. NAME OF THE MEDICINAL PRODUCT

LINCOCIN® Injection 300 mg/mL
LINCOCIN® Injection 600 mg/2 mL
LINCOCIN® Capsules 500 mg
LINCOCIN® Syrup 250 mg/5ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

LINCOCIN hard capsules:
Dark blue (cap) and light blue (body) hard capsules, containing white powder **a**nd branded with "P&U 500" on both parts..
One hard capsule contains 500 mg lincomycin as lincomycin hydrochlorate.

LINCOCIN syrup:
Lightly coloured viscous syrup with raspberry flavour.
One ml of syrup contains 50 mg lincomycin as lincomycin hydrochlorate.

LINCOCIN solution injection:
Colourless solution.
One ml of solution for injection contains 300 mg lincomycin as lincomycin hydrochlorate.

Excipients with known effect:

LINCOCIN hard capsules
The hard capsules contain lactose (see section 4.4).

LINCOCIN syrup
The syrup contains parabens: each ml contains 0.75 mg methylparahydroxybenzoat and 0.25 mg propylparahydroxybenzoat (see section 4.4).
The syrup contains also sucrose (650 mg/ml) (see section 4.4).

LINCOCIN solution injection
The solution for injection contains 9.45 mg benzyl alcohol in each ml (see section 4.4).

For the full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Hard capsules
Syrup
Solution for Injection

4. CLINICAL PARTICULARS

4.1. THERAPEUTIC INDICATIONS

LINCOCIN® is indicated in the treatment of serious infections, when caused by lincomycin susceptible strains of gram-positive aerobes such as streptococci, pneumococci and staphylococci, or by susceptible anaerobic bacteria:

1. Upper respiratory tract infections: chronic sinusitis caused by anaerobic strains.
   Lincomycin can be used for selected cases of chronic suppurative otitis media or as adjunctive therapy along with an antibiotic active against aerobic gram-negative organisms. Infections caused by H. influenzae are no indication (see section 5.1).
2. Lower respiratory tract infections including infectious exacerbation of chronic bronchitis and pneumonia.
3. Serious skin and soft tissue infections caused by susceptible organisms, when penicillins are not indicated.
4. Bone and joint infections including osteomyelitis and septic arthritis.
5. Septicemia and endocarditis.
   Selected cases of septicaemia and/or endocarditis due to susceptible organisms have responded well to lincomycin. However, bactericidal drugs are often preferred for these infections.

4.2. POSOLOGY AND METHOD OF ADMINISTRATION

Dose and method of administration should be determined by the severity of the infection, the condition of the patient, and the susceptibility of the bacteria.
Lincomycin should never be injected intravenously undiluted as a bolus, but should be infused over at least 1 hour (see section "Dilution and infusion rates").

Posology

Adults

A. Oral
   500 mg 3 to 4 times per day preferably 1 or 2 hours before or after the meal. Hard capsules must be swallowed with a sufficient quantity of water.

B. Intravenous injection (see section "Dilution and infusion rates")
   600 mg to 1 gram every 8 to 12 hours.
   These doses may be increased, depending on the severity of the infection.
   In life-threatening situations, daily intravenous doses of as much as 8 grams are given.

Paediatric population

A. Oral
   30 to 60 mg/kg/day divided into 3 or 4 equal doses, preferably 1 or 2 hours before or after a meal.
   Hard capsules must be swallowed with a sufficient quantity of water.

B. Intravenous injection
   10 to 20 mg/kg/day depending on the severity of the infection may be infused in divided doses as described in the section "Dilution and infusion rates".

LINCOCIN solution for injection should only be used in neonates if it is necessary and if there are no alternatives available. LINCOCIN solution for injection should not be used for more than 1 week in children under 3 years old unless necessary (see section 4.4).

POSOLOGY IN CASE OF IMPAIRED RENAL AND/OR LIVER FUNCTION
When therapy with lincomycin is required in patients with severe impairment of renal and/or liver function, the appropriate dose is 25 to 30 % of the dose recommended for patients with normally functioning kidneys/liver.

DILUTION AND INFUSION RATES
Intravenous doses are given on the basis of 1 gram of lincomycin diluted in not less than 100 ml of appropriate solution (such as 0.9 % sodium chloride or 5 % glucose) and infused over a period of not less than 1 hour.

Dose	Volume	Time
600 mg	100 ml	1 hr
1 g	100 ml	1 hr
2 g	200 ml	2 hr
3 g	300 ml	3 hr
4 g	400 ml	4 hr

These doses may be repeated as often as required without exceeding a daily dose of 8 grams of lincomycin.

Note:
Severe cardiopulmonary reactions have occurred when this drug has been given at greater than the recommended concentration and infusion rate.

Throw away the syringe after use: do not reuse.

Lincomycin should never be injected intravenously undiluted as a bolus, but should be infused over at least 1 hour (see section 4.2 “Dilution and infusion rates”).

Method of administration

Oral use
Intravenous use

4.3. CONTRAINDICATIONS

- Hypersensitivity to the active substance, to any of the excipients listed in section 6.1 or to clindamycin.
- In case of meningitis (see sections 4.4 and 5.2).

4.4. SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Severe hypersensitivity reactions, including anaphylactic reactions and severe cutaneous adverse reactions (SCAR) such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), acute generalised exanthematous pustulosis (AGEP), and erythema multiforme (EM) have been reported in

patients receiving lincomycin therapy. If an anaphylactic reaction or severe skin reaction occurs, lincomycin should be discontinued and appropriate therapy should be initiated (see section 4.8).

Clostridium difficile associated diarrhoea (CDAD) has been reported with use of nearly all antibacterial agents, including lincomycin, 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* that produces toxins A and B. CDAD can occur as a mild and aqueous diarrhoea but can also evolve into a severe and persistent diarrhoea, leucocytosis, fever, severe abdominal cramps, and mucus or blood in the stools. If untreated, the patient may develop a potentially fatal peritonitis, shock and toxic megacolon. Medicinal products inhibiting the peristalsis are contraindicated in this clinical situation.

CDAD is more frequent and more severe in enfeebled or aged subjects. Hypertoxin producing strains of *C. difficile* can also be associated with increased morbidity and mortality.

CDAD must be considered in all patients who present with diarrhoea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents. The diagnosis is generally based on clinical symptoms but it can also be confirmed by endoscopy or the identification of *Clostridium difficile* and its toxins in the stools (see section 4.8).

Lincomycin should be prescribed with caution in subjects with history of gastrointestinal disorders, especially colitis.

Excipients with known effect:
The syrup contains parabens which may cause allergic reactions (sometimes delayed).
The syrup contains also sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
The syrup contains sodium. This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially ‘sodium-free’.

The hard capsules contain lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.
The hard capsules contain sodium. This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially ‘sodium-free’.

The injectable form of this product contains benzyl alcohol (9.45 mg/ml) (see section 2).
The preservative benzyl alcohol may cause hypersensitivity reactions.
Intravenous administration of the preservative benzyl alcohol has been associated with serious adverse events, and death in paediatric patients including neonates characterized by central nervous system depression, metabolic acidosis, gasping respirations, cardio-vascular failure and haematological anomalies (“gasping syndrome”). Although normal therapeutic doses of this product ordinarily deliver amounts of benzyl alcohol that are substantially lower than those reported in association with the “gasping syndrome”, the minimum amount of benzyl alcohol at which toxicity may occur is not known. Benzyl alcohol containing formulations should only be used in neonates if it is necessary and if there are no alternatives possible. Benzyl alcohol containing formulations should not be used for more than 1 week in children under 3 years of age unless necessary. If use of a benzyl alcohol-containing formulation of lincomycine is necessary, it is important to consider the combined daily metabolic load of benzyl alcohol from all sources, especially in patients with liver or kidney impairment, as well as in pregnant or breast-feeding women, because of the risk of accumulation and toxicity (metabolic acidosis). Premature and

low-birth weight infants may be more likely to develop toxicity. Benzyl alcohol containing products should not be used in pre-term or full-term neonates unless strictly necessary.

Lincomycin should not be used in the treatment of meningitis as its levels in cerebrospinal fluid are inadequate (see sections 4.3 and 5.2).

In vitro, antagonism has been demonstrated between lincomycin and erythromycin or chemical related macrolides. Because of possible clinical significance, these two drugs should not be administered concurrently.

Hepatic and renal function should be monitored during prolonged treatments.

The use of lincomycin may result in overgrowth of non-susceptible organisms, particularly yeasts.

Lincomycin should never be injected intravenously undiluted as a bolus, but should be infused over at least 1 hour (see section 4.2).

Lincomycin has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. Therefore, lincomycin should be used with caution in patients receiving such agents.

Lincomycin should be administered with caution in atopic patients.

Lincomycin should be used with caution in patients with severe renal and/or severe hepatic disorders associated with severe metabolic abnormalities: dose should be adapted (see section 4.2). During high-dose therapy the serum lincomycin levels should be monitored as serum half-life may be 2 to 3 fold longer in these patients.

Because of the potential for severe reactions to lincomycin in nursing infants, a decision should be made either to discontinue breast-feeding or drug therapy taking into account the importance of the drug for the mother (see section 4.6).

4.5. INTERACTION WITH OTHER MEDICAMENTS AND OTHER FORMS OF INTERACTION

The action of neuromuscular blockers can be increased (see section 4.4).

Simultaneous orally administered kaolin-pectin mixtures inhibit the absorption of lincomycin by as much as 90 %. These mixtures should be given at least 2 hours before or 3 to 4 hours after lincomycin to avoid such an interaction.

In vitro, antagonism has been demonstrated between lincomycin, erythromycin and chemical related macrolides. Because of possible clinical significance, these two drugs should not be administered concurrently.

Lincomycin can interfere with the plasma levels of alkaline phosphatase. Consequently the obtained values can be erroneously elevated.

4.6. FERTILITY, PREGNANCY AND LACTATION

Pregnancy

Animal studies do not indicate reproductive toxicity (see section 5.3).

There are limited data on the use of lincomycin in pregnant women. The progeny of 302 patients treated with lincomycin at various stages of pregnancy showed no increases in congenital anomalies or delayed development compared to a control group for up to 7 years after birth.

In humans, lincomycin crosses the placenta and results in cord serum levels about 25% of the maternal serum levels. No significant accumulation occurs in the amniotic fluid.

As a precaution, it is preferable to avoid the use of lincomycin during pregnancy except if treatment is really needed.

The following statement applies only for LINCOCIN solution for injection : Benzyl alcohol can cross the placenta (see section 4.4).

Breastfeeding

Because of the potential for severe reactions to lincomycin in nursing infants, a decision should be made whether to discontinue breast-feeding or to discontinue drug therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the mother (see section 4.4).

LINCOCIN solution for injection contains benzyl alcohol as a preservative. Benzyl alcohol present in maternal serum is likely to cross into human milk and may be orally absorbed by a nursing infant (see section 4.4).

Fertility

There were no effects on fertility in animal studies (see section 5.3). Clinical data on male and female fertility are not available.

4.7. EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No studies were conducted to determine the effect of lincomycin on ability to drive and use machines. Although no specific effect on ability to drive and use machines has been observed, occasional cases of dizziness have been reported.

4.8. UNDESIRABLE EFFECTS

Summary of the safety profile:
The most common undesirable effects are gastrointestinal adverse events (diarrhoea, nausea, and vomiting).

The table below lists the adverse reactions identified through clinical trials and post-marketing surveillance by system organ class and frequency. Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Table of adverse reactions

System organ class	**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)**	**Frequency not known *(cannot be estimated from the available data)***
Infections and infestations			Vaginal infection			Pseudomembranous colitis, *Clostridium difficile* colitis
Blood and lymphatic system disorders						Pancytopoenia, agranulocytosis, aplastic anaemia, neutropoenia, leukopoenia, thrombocytopoenic purpura
Immune system disorders						Anaphylactic reactions, angio-oedema, serum sickness
Cardiac disorders						Cardio-respiratory[a] Arrhythmias
Vascular disorders						Hypotension[b], thrombophlebitis[c]
Gastrointestinal disorders		Diarrhoea, nausea, vomiting				Oesophagitis[d], abdominal discomfort
Hepatobiliary disorders						Jaundice, liver function test abnormal
Skin and subcutaneous tissue disorders			Skin rash, urticaria	Pruritus		Toxic epidermal necrolysis (TEN),, Acute generalised exanthematous pustulosis (AGEP), Steven-Johnson syndrome, dermatitis bullous, dermatitis exfoliative, erythema multiforme

a Rare cases have been reported after too rapid intravenous administration.
b Following parenteral administration, particularly after too rapid administration.
c Event has been reported with intravenous injection.
d Event has been reported with oral preparation..
e Rare instances of arrhythmias have been reported after too rapid intravenous administration of high doses of the drug.

Description of selected adverse reactions:

Clostridium difficile associated diarrhea: Almost all antibiotics, among which are penicillins, cephalosporins and lincosamides, can give rise to severe diarrhoea (sometimes after a latency period), colitis and pseudomembranous colitis, caused by toxins of *Clostridium difficile*. If diarrhoea occurs during treatment, the drug should be discontinued. Colitis may also occur until 2-3 weeks after discontinuing treatment. Drugs which inhibit intestinal peristaltism should be avoided (see section 4.4).

Pediatric population

The injectable form of this product contains benzyl alcohol (see section 4.4).

Other special populations

Patients with severe renal and/or hepatic impairment: lincomycin should be used with caution in patients with severe renal impairment and/or severe hepatic impairment associated with serious metabolic abnormalities; the dose should be reduced in these populations (see sections 4.2 and 4.4).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important, as it allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

4.9. OVERDOSE

In cases of overdosage, gastrointestinal disorders including abdominal pain, nausea, vomiting and diarrhoea may occur. Cases of cardiopulmonary arrest have been reported when IV doses were given rapidly without dilution. These reactions do not occur when the drug is diluted in accordance with instructions mentioned in section 4.2. Overdosage may be treated with emesis or gastric lavage, if indicated. No specific antidote is known. Haemodialysis and peritoneal dialysis are not effective in removing lincomycin from the serum.

5. PHARMACOLOGICAL PROPERTIES

5.1. PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Lincomycin is a lincosamide antibiotic
ATC code: J01FF02.

Mechanism of action

Lincomycin binds to the 50S subunit of the bacterial ribosome and inhibits protein synthesis. Lincomycin has a predominantly bacteriostatic action.

PK/PD relationship

Efficacy is related to the time period that the agent level is above the minimum inhibitory concentration (MIC) of the pathogen (%T/MIC).

Mechanism(s) of resistance

Cross resistance between lincomycin and clindamycin is complete. Resistance in staphylococci and streptococci is most often due to methylation of specific nucleotides in the 23S RNA of the 50S ribosomal subunit, which can determine cross resistance to macrolides and streptogramins B (MLS_B phenotype). Macrolide-resistant isolates of these organisms should be tested for inducible resistance to lincomycin/clindamycin using the D-zone test.

Susceptibility testing breakpoints

Because the European Committee on Antimicrobial Susceptibility Testing (EUCAST) has not established susceptibility breakpoints for lincomycin, clindamycin should be tested instead. Resistance to lincosamides may be inducible by macrolides in macrolide-resistant staphylococci, *Streptococcus pneumoniae,* and beta-hemolytic streptococci. Macrolide-resistant isolates of these organisms should be screened for inducible clindamycin resistance using the D-zone test or other standard methodology.

EUCAST Breakpoints for clindamycin

Organism	**Minimal Inhibitory Concentrations (MIC in mg/L)**	
	S	**R**
Staphylococcus spp.	≤ 0.25	> 0.5
Streptococcus groups A, B, C, G	≤ 0.5	> 0.5
Streptococcus pneumoniae	≤ 0.5	> 0.5
Viridans group streptococci	≤ 0.5	> 0.5
Gram-positive anaerobes (except *Clostridium difficile*)	≤ 4	> 4

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 on 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 lincomycin/clindamycin is recommended.

The following data is available for clindamycin based on European surveillance studies available in 2013.

Commonly susceptible organisms	**Remarks**
Aerobic gram-positive microorganisms	
Actinomyces israelii[a]	

Staphylococcus aureus (methicillin-susceptible	
Streptococcus agalactiae	
Viridans group streptococci	
Anaerobic microorganisms	
Bacteroides spp.[a] (excluding *B. fragilis*)	
Fusobacterium spp.[a]	
Peptococcus spp.[a]	
Prevotella spp.	
Veillonella spp.[a]	
Other microorganisms	
Chlamydia trachomatis[a]	
Clamydophila pneumoniae[a]	
Gardnerella vaginalis[a]	
Mycoplasma hominis[a]	

Organisms for which acquired resistance may be a problem	**Remarks**
Aerobic gram-positive microorganisms	
Staphylococcus aureus (methicillin-resistant)[b]	
Staphylococcus epidermidis[b]	
Staphylococcus haemolyticus	
Staphylococcus hominis	
Streptococcus pneumoniae	Resistance rates between >20 and 49 % in some European countries
Aerobic gram-negative microorganisms	
Moraxella catarrhalis[c]	
Anaerobic microorganisms	
Bacteroides fragilis	
Clostridium perfringens	Higher resistance rates in Spain (10-20 %)
Peptostreptococcus spp.	Higher resistance rates in Spain (10-20 %)
Propionibacterium spp.	

Inherently resistant organisms	**Remarks**
Aerobic gram-positive microorganisms	
Enterococcus spp.	
Listeria monocytogenes	
Aerobic gram-negative microorganisms	
Escherichia coli	
Klebsiella spp.	
Neisseria gonorrhoeae	
Pseudomonas aeruginosa	
Anaerobic microorganisms	
Clostridium difficile	
Other microorganisms	
Mycoplasma pneumoniae	
Ureaplasma urealyticum	

[a] Updated information not available.

[b] At least one European region has reported resistance rates higher than 50 %.

[c] Most isolates have inherently intermediate resistance.

5.2. PHARMACOKINETIC PROPERTIES

Absorption

Oral administration of a single 500 mg dose of lincomycin in the fasting state produces peak serum level of 2.8 to 5.3 µg/mL at 2 to 4 hours post-dose. The oral bioavailability is estimated to be 20-35 % under fasting state. Administration immediately after a meal reduces oral absorption by approximately 50 %.

Intramuscular administration of a single 600 mg dose of lincomycin produces a mean maximum serum concentration of 11.6 µg/mL at 60 minutes and maintains therapeutic levels for 17-20 hours for the most susceptible gram-positive organisms.

An intravenous infusion of 600 mg of lincomycin over two hours obtains a mean maximum serum concentration of 15.9 µg/mL and therapeutic concentrations over 14 hours for the most susceptible Gram-positive organisms.

Distribution

Lincomycin is approximately 72 % bound to plasma proteins. Published studies indicate that plasma protein binding is saturable; consequently, percentage of protein bound drug decreases with higher serum concentrations.

Lincomycin is distributed widely throughout the body, without apparent concentration in any particular organ. Diffusion in bone tissue is excellent.

In foetal blood and in peritoneal and pleural liquid concentrations of 25-50 % of the blood levels can be reached, in the mother milk 50-100 %, in the bone tissues about 40 % and in soft tissues 75 %. Lincomycin passes into breast milk. Lincomycin crosses the blood-brain and the placental barrier. Although lincomycin appears to diffuse in cerebrospinal fluid (CSF), lincomycin levels in CSF appear inadequate for the treatment of meningitis (see sections 4.3 and 4.4)

Biotransformation

Lincomycin is metabolised by the liver.

Elimination

The plasma half-life of lincomycin is between 4 and 6 hours on average.

Lincomycin is excreted in the urine and the bile, and is also found in the faeces. Biliary excretion is high, with concentrations about ten times greater than in blood.

Urinary excretion varies according to the mode of administration. Following single oral administration of 500 mg lincomycin, urinary excretion of lincomycin ranges from 1.8 to 13.7 % (mean 6.2 %). After single IM dose of 600 mg, urinary excretion of lincomycin ranges from 1.8 to 24.8 % (mean 10.3 %). In case of two hour IV infusion of 600 mg of lincomycin, urinary excretion ranges from 4.9 to 23.3 % (mean 15.1 %).

Elimination in faeces represents approximately 33% of an oral dose.

Patients with Renal Impairment
The serum half-life of lincomycin may be prolonged in patients with severe impairment of renal function compared to patients with normal renal function. Hemodialysis and peritoneal dialysis are not effective in removing lincomycin from the serum (see section 4.2).

Patients with Hepatic Impairment
In patients with abnormal hepatic function, serum half-life may be two-fold longer than in patients with normal hepatic function (see section 4.2).

5.3. PRECLINICAL SAFETY DATA

Nonclinical data from conventional studies on repeated administration toxicity, genotoxicity, carcinogenesis, and reproductive and developmental toxicity have not identified any particular risks to humans. No developmental toxicity was observed when doses greater than 6x the maximum recommended human dose (MRHD) were administered to pregnant rats during the organogenesis period. No effects on fertility were observed in rats administered lincomycin at 1.2x the MRHD.

6. PHARMACEUTICAL PARTICULARS

6.1. LIST OF EXCIPIENTS

Hard capsules 500 mg
Content of hard capsule: lactose, talc, magnesium stearate.
Hard capsule itself: gelatine, disodium salt of 5,5'-indigotin disulfonic acid**,** titanium dioxide.

Syrup 250 mg/ml
Propylparahydroxybenzoat (E216), methylparahydroxybenzoat (E218), sorbic acid, sodium saccharine, sucrose, synthetic oil of Rubi idaei (der. no. 42/54), synthetic oil of guarana (der. no. 42/55), sodium hydroxide, concentrated hydrochloric acid, purified water.

Solution for Injection 300 mg/ml
Benzyl alcohol; water for injections.

6.2. INCOMPATIBILITIES

Lincomycin is physically incompatible with novobiocin, kanamycin and phenytoin when combined in an infusion solution.

6.3. SHELF LIFE

Pack (Nature & Content of Container)	**Shelf-life**	**Storage Conditions**
5's Clear Glass Ampoule	36 Months	Store below 30ºC (Injection)
14's Blister Foil / Aluminum PVC	36 Months	Store below 30ºC (Capsules)
1's Amber Glass bottle	24 Months	Store below 30ºC (Syrup)

6.4. SPECIAL PRECAUTIONS FOR STORAGE

No special precautions for storage

6.5. NATURE AND CONTENTS OF CONTAINER

LINCOCIN® is available as:

- LINCOCIN® Injection 300 mg/mL in 5's (vials)
- LINCOCIN® Injection 600 mg/2 mL in 5's (vials)
- LINCOCIN® Capsules 500 mg in 12's blister pack
- LINCOCIN® Syrup 250 mg/5 mL in 60 mL bottle

Not all pack sizes may be marketed.

6.6. SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

No special requirements.

6.7. DRUG PRODUCT SPECIFICATIONS

Refer to pack

7. REGISTRATION HOLDER / MARKETING AUTHORIZATION HOLDER:

Pfizer Pakistan Limited

B-2, S.I.T.E., Karachi

Name of Manufacturing site	**Address of site**	**Manufacturing step (if applicable)**
Sanof-aventis Pakistan Ltd	Plot-23, Sector 22, Korangi Industrial Area Karachi	Production Packaging, Testing & Batch release (Injection)
Pfizer Pakistan Limited	B-2, S.I.T.E., Karachi	Batch release (Injection)
Pfizer Pakistan Limited	B-2, S.I.T.E., Karachi	Production Packaging, Testing & Batch release (Capsules & Syrup)

8. REGISTRATION / MARKETING AUTHORIZATION NUMBER:

Lincocin Injection 300mg/mL - Reg. No. 015099

Lincocin Injection 600mg/2mL - Reg. No. 000605

Lincocin HFC Capsules 500mg - Reg. No. 000602

Lincocin Syrup 250mg/5ml - Reg. No. 012301

9. DATE FROM WHICH MARKETING IS AUTHORIZED:

Lincocin Injection 300mg/mL - 19-Jun-1996

Lincocin Injection 600mg/2mL - 05-Aug-1976

Lincocin HFC Capsules 500mg - 05-Aug-1976

Lincocin Syrup 250mg/5ml - 13-Feb-1991

Lincocin/LPD/PK-02
According to Belgium approved SPC dated: 20 May 2023 & approved information in Pakistan

Marketed by:
Pfizer Pakistan Limited

*Please visit our website **www.pfizerpro.com.pk** for latest version of Product leaflet.*