PT. PFIZER INDONESIA
Local Product Document

Generic Name: Lincomycin
Trade Name: LINCOCIN®
CDS Effective Date: February 13, 2018
Supersedes: October 28, 2014

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi

DESCRIPTION

LINCOCIN® Capsules contain lincomycin hydrochloride which is the monohydrated salt of lincomycin, a substance produced by the growth of a member of the *lincolnensis* group of *Streptomyces lincolnensis* (Fam. *Streptomycetaceae*). It is a white or practically white, crystalline powder and is odorless or has a faint odor. Its solutions are acid and are dextrorotatory. Lincomycin hydrochloride is freely soluble in water; soluble in dimethyl-formamide, and very slightly soluble in acetone.

CLINICAL PHARMACOLOGY

Microbiology - Lincomycin has been shown to be effective against most of the common gram-positive pathogens. Depending on the sensitivity of organism and concentration of the antibiotic, it may be either bactericidal or bacteriostatic. Cross resistance has not been demonstrated with penicillin, chloramphenicol, ampicillin, cephalosporins or the tetracyclines. Despite chemical differences, lincomycin exhibits antibacterial activity similar but not identical to the macrolide antibiotics (e.g., erythromycin). Some cross resistance (with erythromycin) including a phenomenon known as dissociated cross resistance or macrolide effect has been reported. Microorganisms have not developed resistance to lincomycin rapidly when tested *in vitro* or *in vivo* methods. Staphylococci developed resistance to lincomycin in a slow, stepwise manner based on *in vitro*, serial subculture experiments. This pattern of resistance development is unlike that shown for streptomycin.

Studies indicate that lincomycin does not share antigenicity with penicillin compounds.

Biological Studies - *In vitro* studies indicate that the spectrum of activity includes *Staphylococcus aureus*, *Staphylococcus albus*, *β-hemolytic Streptococcus*, *Streptococcus viridans*, *Diplococcus pneumoniae*, *Clostridium tetani*, *Clostridium perfringens*, *Corynebacterium diphteriae* and *Corynebacterium acnes*.

NOTE: this drug is not active against most strains of *Streptococcus faecalis*, nor against *Neisseria gonorrhoeae*, *Neisseria meningitidis*, *Hemophilus influenzae*, or other gram-negative organism of yeasts.

Human Pharmacology - Lincomycin is absorbed rapidly after a 500 mg oral dose, reaching peak levels in 2 to 4 hours. Levels are maintained above the Minimum Inhibitory Concentration (MIC) for most gram-positive organisms for 6 to 8 hours. Urinary recovery of drug in a 24-hour period ranges from 1.0 to 31 percent (mean: 4.0) after a single oral dose of 500 mg of lincomycin. Tissue level studies indicate that bile is an important route of excretion. Significant levels have been demonstrated in the majority of body tissues. Although the drug is not present in significant amounts in the spinal fluid of normal volunteers, it has been demonstrated in the spinal fluid of one patient with pneumococcal meningitis.

Intramuscular administration of a single dose of 600 mg of lincomycin produces a peak serum level at 30 minutes with detectable levels persisting for 24 hours. Urinary excretion after this dose ranges from 1.8 to 24.8 percent (mean: 17.3)

The intravenous infusion over a 2-hour interval of 600 mg of lincomycin in 500 ml of 5 percent glucose in distilled water yields therapeutic levels for 14 hours. Urinary excretion ranges from 4.9 to 30.3 percent (mean 13.8)

The biological half-life, after oral, intramuscular or intravenous administration is 5.4 ± 1.0 hours.

Hemodialysis and peritoneal dialysis do not effectively remove lincomycin from the blood.

Pharmacodynamic Properties

Mode of Action:

Lincomycin is an antibiotic produced by fermentation of *Streptomyces lincolnensis*. Lincomycin inhibits bacterial protein synthesis by binding to the 50S subunit of the bacterial ribosome. Lincomycin is predominantly bacteriostatic *in vitro*. The antibacterial activity of lincomycin appears to best correlate with the length of time the concentration of active ingredient remains above the MIC of the infecting organism.

Mechanism 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.

Antibacterial Spectrum

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.

Lincomycin is cross-resistant with clindamycin. A decrease in clindamycin/lincomycin susceptibility over time has been noted in particular among methicillin-resistant *Staphylococcus aureus*.

Antimicrobial Activity
Lincomycin has been shown to be active against most strains of the following bacteria **both *in vitro* and in clinical infections:** (see Section **INDICATIONS AND USAGE**).

Staphylococcus aureus
Streptococcus pneumoniae

The following *in vitro* data are available, but their clinical significance is unknown.

Lincomycin has been shown to be active *in vitro* against the following microorganisms; however, the safety and efficacy of LINCOCIN® in treating clinical infections due to these organisms have not been established in adequate and well controlled trials.

Gram-positive bacteria:
Corynebacterium diphtheriae
Streptococcus pyogenes
Viridans group streptococci

Anaerobic bacteria:
Clostridium tetani
Clostridium perfringens

Pharmacokinetic Properties
Oral administration of a single 500 mg dose of lincomycin in the fasting state produces an average peak serum level of 5.3 µg/mL at 2 hours post-dose. Administration immediately after a meal reduces oral absorption.

Tissue level studies indicate that bile is an important route of excretion. Significant levels have been demonstrated in the majority of body tissues. Although lincomycin appears to diffuse into cerebrospinal fluid (CSF), levels of lincomycin in the CSF appear inadequate for the treatment of meningitis.

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.

INDICATION AND USAGE
LINCOCIN® is indicated in the treatment of serious infections due to susceptible strains of streptococci, pneumococci and staphylococci. Its use should be reserved for penicillin-allergic patients or where therapy with penicillin is inappropriate. Because of

the risk of severe colitis, the nature of infection and the suitability of less toxic alternatives (e.g., erythromycin) should be considered before selecting lincomycin.

CONTRAINDICATIONS
LINCOCIN® is contraindicated in patients previously found sensitive to lincomycin or clindamycin or to any other component of the product. It is not indicated in the treatment of minor bacterial infections or viral infections.

WARNINGS
Lincomycin therapy, like therapy with other broad spectrum antibiotics, has been associated with pseudomembranous colitis which may end fatally. Therefore it should be reserved for serious infections where less toxic antimicrobial agents are inappropriate, as described in INDICATIONS AND USAGE section. Diarrhea, colitis, and pseudomembranous colitis have been observed to begin up to several weeks following cessation of therapy with lincomycin. Consequently, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of lincomycin.

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 **ADVERSE REACTIONS**).

Treatment with antibiotics alters the normal flora of the colon and may permit the overgrowth of clostridia. Studies indicate a toxin produced by *Clostridium difficile* is the primary cause of “antibiotic-associated colitis”.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including lincomycin, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile.*

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated.

Mild cases of colitis may respond to drug discontinuance alone. Moderate to severe cases should be managed promptly with fluids, electrolytes and protein supplementation as indicated and be treated with an antibacterial drug clinically effective against *Clostridium difficile* colitis. Vancomycin has been found to be

effective in the treatment of antibiotic associated pseudomembranous colitis produced by *Clostridium difficile*. The usual adult dose is 500 mg to 2 g of vancomycin orally per day in three to four divided doses administered for 7 to 10 days. Cholestyramine or colestipol resins bind vancomycin *in vitro*. If both a resin and vancomycin are to be administered concurrently, it may be advisable to separate the time of administration of each drug. Systemic corticoids and corticoid retention enemas may help relieve the colitis. Other causes of colitis should also be considered.

Although lincomycin appears to diffuse into cerebrospinal fluid, levels of lincomycin in the CSF may be inadequate for the treatment of meningitis. Thus, the drug should not be used in the treatment of meningitis.

A careful inquiry should be made concerning previous sensitivities to drugs and other allergens.

Usage in Pregnancy - Safety for use in pregnancy has not been established.

Usage in Newborn - Until further clinical experience is obtained, LINCOCIN® preparations (lincomycin) are not indicated in the newborn.

Nursing Mothers - Lincomycin has been reported to appear in breast milk in ranges of 0.5 to 2.4 mcg/ml.

PRECAUTIONS

Review of experience to date suggests that a subgroup of older patients with associated severe illness may tolerate diarrhea less well. When LINCOCIN® preparations (lincomycin) are indicated in these patients, they should be carefully monitored for change in bowel frequency.

LINCOCIN® should be prescribed with caution in individuals with a history of gastrointestinal disease particularly colitis.

LINCOCIN® like any drug, should be used with caution in patients with a history of asthma or significant allergies.

The use of antibiotics occasionally results in overgrowth of non-susceptible organisms, particularly yeasts. Should superinfections occur, appropriate measures should be taken. When patients with pre-existing monilial infections require therapy with LINCOCIN®, concomitant antimonilial treatment should be given.

During prolonged therapy with LINCOCIN®, periodic liver and renal function studies and blood counts should be performed.

Since adequate data are not yet available in patients with pre-existing liver disease, its use in such patients is not recommended at this time unless special clinical circumstances so indicate.

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

Indicated surgical procedures should be performed in conjunction with antibiotic therapy.

FERTILITY, PREGNANCY AND LACTATION
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. 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. Lincomycin should be used during pregnancy only if clearly needed.

Lincomycin has been reported to appear in human breast milk in concentrations of 0.5 to 2.4 mcg/ml.

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.

ADVERSE REACTIONS
Gastrointestinal - Glossitis, stomatitis, enterocolitis, and pruritus ani.

Renal - Renal dysfunction as evidenced by azotemia, oliguria, and/or proteinuria has been observed in rare instances.

Adverse Reactions Table: ADRs by SOC and CIOMS frequency category listed in order of decreasing medical seriousness or clinical importance within each frequency category and SOC

System Organ Class	**Very Common (≥1/10)**	**Common (≥1/100 to <1/10)**	**Uncommon (≥1/1000 to <1/100)**	**Rare (≥1/10,000 to <1/1000)**	**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						Pancytopenia, Agranulocytosis, Aplastic anaemia, Neutropenia, Leukopenia, Thrombocytopenic purpura
Immune system disorders						Anaphylactic reaction, Angioedema, Serum sickness
Cardiac disorders						Cardio-respiratory arrest[a]

Adverse Reactions Table: ADRs by SOC and CIOMS frequency category listed in order of decreasing medical seriousness or clinical importance within each frequency category and SOC

System Organ Class	Very Common (≥1/10)	Common (≥1/100 to <1/10)	Uncommon (≥1/1000 to <1/100)	Rare (≥1/10,000 to <1/1000)	Very Rare (<1/10,000)	Frequency Not Known *(Cannot be Estimated from the Available Data)*
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			Rash, Urticaria	Pruritus		Toxic epidermal necrolysis Stevens-Johnson syndrome, Acute generalised exanthematous pustulosis Dermatitis bullous, Dermatitis exfoliative, Erythema multiforme
General disorders and administration site conditions						Injection site abscess sterile[e], Injection site induration[e], Injection site pain[e], Injection site irritation[e]

a. Rare instances 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 preparations.
e. Reported with intramuscular injection.

INTERACTIONS

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.

OVERDOSE

Hemodialysis or peritoneal dialysis do not effectively remove lincomycin from the blood.

DOSAGE AND ADMINISTRATION

If significant diarrhea occurs during therapy, this antibiotic should be discontinued (see **WARNING** section).

ORAL - Adults: Serious infections due to susceptible organisms, 500 mg 3 times per day (every 8 hours). More severe infections, 500 mg 4 times per day (every 6 hours).
Children over 1 month of age: Serious infections, 30 mg/kg/day divided into 3 or 4 equal doses. More severe infections, 60 mg/kg/day divided into 3 or 4 equal doses.

In cases of β-hemolytic streptococcal infections, treatment should be continued for at least 10 days.

Note: For optimal absorption, it is recommended that nothing be given by mouth for a period of 1 to 2 hours before and after oral administration of lincomycin.

Dosage in Patients with Diminished Hepatic or Renal Function
In patients with impaired hepatic function or impaired renal function, lincomycin's serum half-life is increased. Consideration should be given to decreasing the frequency of administration of lincomycin in patients with impaired hepatic or renal function.

Patients with diminished renal function: When therapy with LINCOCIN® is required in individuals with severe impairment of renal function, an appropriate dose is 25% to 30% of that recommended for patients with normally functioning kidneys.

ANIMAL PHARMACOLOGY
In vivo experimental animal studies demonstrated the effectiveness of LINCOCIN® preparations (lincomycin) in protecting animals infected with *Streptococcus viridans*, *β-hemolytic-Streptococcus*, *Staphylococcus aureus*, *Diplococcus pneumoniae*, and *Leptospira pomona*. It was ineffective in *Klebsiella*, *Pasteurella*, *Pseudomonas*, *Salmonella*, and *Shigella* infections.

CLINICAL STUDIES
Experience with 345 obstetrical patients receiving this drug revealed no ill effects related to pregnancy.

PHARMACEUTICAL PARTICULARS
List of excipients:
Lactose, talc, magnesium stearate and hard gelatin capsule shells.

The opaque dark blue color cap capsule shell components contain gelatin, FD&C blue 1, ponceau 4R, and titanium dioxide.

The opaque light blue body capsule shell components contain gelatin, FD&C blue 1, FD&C Red 40, and titanium dioxide.

HOW SUPPLIED
LINCOCIN® Capsules contain lincomycin hydrochloride equivalent to 500 mg of lincomycin.

LINCOCIN® 500 mg; Box, 3 blisters @ 10 capsules; Reg No.: DKL7219808601A1

Store at maximum temperature 30°C.

HARUS DENGAN RESEP DOKTER

Manufactured by

PT. Pfizer Indonesia
Jakarta, Indonesia

Leaflet kemasan: Informasi untuk pengguna

Lincocin®
Kapsul 500 mg
Linkomisin hidroklorida

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi

Baca semua bagian leaflet ini dengan cermat sebelum mulai menggunakan obat ini karena berisi informasi penting bagi Anda.
- Simpan leaflet ini. Anda mungkin perlu membacanya kembali.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter, apoteker, atau perawat Anda.
- Obat ini telah diresepkan hanya untuk Anda. Jangan berikan kepada orang lain. Obat ini dapat membahayakan mereka, sekalipun tanda-tanda penyakit mereka sama dengan Anda.
- Jika Anda mengalami efek samping apa pun, konsultasikan dengan dokter atau perawat Anda. Termasuk setiap kemungkinan efek samping yang tidak tercantum dalam leaflet ini. Lihat bagian 13.

Isi leaflet ini:

1. Nama obat
Lincocin®

2. Bentuk sediaan
Kapsul

3. Deskripsi obat
Lincocin® 500 mg kapsul mengandung linkomisin hidroklorida yang merupakan garam monohidrat dari linkomisin. Obat ini berupa serbuk kristalin berwarna putih atau hampir putih dan tanpa bau atau memiliki sedikit bau.

4. Apa kandungan obat ini?
Setiap kapsul Lincocin® mengandung linkomisin hidroklorida yang setara dengan 500 mg linkomisin.

Bahan-bahan lainnya adalah:
Isi kapsul: laktosa, talk, dan magnesium stearate.
Cangkang tutup kapsul: gelatin, FD&C blue 1, ponceau 4R, dan titanium dioksida.
Cangkang badan kapsul: gelatin, FD&C blue 1, FD&C Red 40, dan titanium dioksida.

5. Kekuatan obat
500 mg.

6. Apa kegunaan obat ini?
Lincocin® adalah antibiotik yang digunakan untuk mengobati infeksi bakteri serius.

7. Berapa banyak dan seberapa sering Anda seharusnya menggunakan obat ini? Apa yang harus dilakukan jika ada dosis yang terlewat?
Selalu gunakan obat ini dengan tepat sesuai anjuran dokter atau apoteker Anda. Tanyakan kepada
dokter atau apoteker jika Anda merasa tidak yakin.

Lincocin® harus selalu ditelan utuh dengan segelas air penuh.

Orang Dewasa
Dosis yang dianjurkan untuk Lincocin® adalah antara 500 mg (1 kapsul) setiap 8 jam hingga setiap 6 jam, bergantung pada seberapa berat infeksi Anda.

Penggunaan pada anak-anak berusia lebih dari 1 bulan
Dosis yang dianjurkan untuk anak-anak adalah mulai 30 hingga 60 mg/kg/hari terhadap berat badan, yang dibagi menjadi 3 atau 4 dosis yang sama, bergantung pada beratnya infeksi.

Dokter Anda akan menentukan jumlah kapsul yang harus diminum oleh anak Anda. Jika anak Anda tidak dapat menelan kapsul, konsultasikan dengan dokter atau apoteker Anda.

Dianjurkan untuk tidak memberikan apa pun melalui mulut selama periode 1 hingga 2 jam sebelum dan sesudah pemberian linkomisin secara oral.

Penggunaan Lincocin® untuk jangka panjang
Jika Anda harus meminum Lincocin untuk jangka panjang, dokter Anda mungkin akan melakukan tes darah, ginjal, dan hati secara rutin. Jangan melewatkan jadwal pemeriksaan ini dengan dokter Anda.

Penggunaan jangka panjang juga dapat menyebabkan Anda lebih rentan terkena infeksi lainnya yang tidak merespons pengobatan dengan Lincocin®.

Jika Anda lupa meminum Lincocin®

Jika dosis yang terlupa hanya terlambat beberapa jam, segera gunakan. Jika hampir mencapai waktu untuk dosis yang Anda berikutnya, lewatkan dosis yang terlupa. **Jangan meminum dosis ganda untuk mengejar dosis yang tertinggal.**

Jika Anda berhenti meminum Lincocin®

Jika Anda berhenti meminum obat terlalu cepat, infeksi Anda dapat kembali lagi atau semakin memburuk.

Jangan berhenti meminum Lincocin® kecuali atas arahan dokter.

Jika Anda memiliki pertanyaan lebih lanjut seputar penggunaan obat ini, tanyakan kepada dokter atau apoteker Anda.

8. Kapan seharusnya Anda tidak menggunakan obat ini?

Jangan menggunakan Lincocin®

- Jika Anda alergi (hipersensitif) terhadap linkomisin, klindamisin, atau bahan apa pun lainnya dalam obat ini.
- Jika Anda menderita infeksi bakteri atau infeksi virus ringan.

9. Apa pertimbangan saat menggunakan obat ini?

Konsultasikan dengan dokter Anda sebelum menggunakan Lincocin® jika:

- Anda mengalami diare atau biasanya mengalami diare saat Anda meminum antibiotik atau pernah mengalami gangguan pada lambung atau usus Anda. Jika Anda mengalami diare berat atau berkepanjangan atau berdarah selama atau setelah menggunakan Lincocin® **segera beri tahu dokter Anda** karena pengobatan Anda mungkin perlu ditangguhkan. Kondisi ini bisa jadi merupakan tanda-tanda peradangan usus (kolitis pseudomembran) yang dapat terjadi setelah menjalani pengobatan dengan antibiotik.
- Anda menderita gangguan pada ginjal atau hati.
- Anda menderita asma, eksem, atau hayfever (alergi serbuk bunga).
- Anda mengalami reaksi kulit yang berat atau hipersensitif terhadap Lincocin®.

Meskipun Lincocin® mengalir masuk ke otak, tetapi obat ini tidak sesuai untuk mengobati infeksi serius di dalam dan di sekitar otak. Dokter Anda mungkin perlu memberi Anda antibiotik lain jika Anda mengalami infeksi ini.

10. Apa saja obat lain atau makanan yang harus dihindari selama menggunakan obat ini?

Beri tahu dokter atau apoteker Anda jika Anda sedang meminum, baru-baru ini meminum atau mungkin akan meminum obat-obatan lainnya:

- relaksan otot yang digunakan untuk operasi (pemblokir neuromuskular).

11. Apakah obat tersebut aman bagi ibu hamil dan menyusui?

Kehamilan

Jika Anda sedang hamil atau merasa diri Anda mungkin hamil, segera hubungi dokter sebelum meminum Lincocin®.

Mintalah saran dari dokter atau apoteker Anda sebelum meminum obat apa pun.

Menyusui
Beri tahu dokter Anda jika Anda akan menyusui selama meminum Lincocin® karena linkomisin dapat dialirkan ke dalam ASI. Dokter Anda akan memutuskan apakah Lincocin® sesuai untuk Anda.

Meskipun kecil kemungkinan bagi bayi yang menerima ASI untuk memperoleh zat aktif yang banyak dari ASI yang diminumnya, tetapi jika bayi Anda mengalami diare berdarah atau menunjukkan tanda-tanda sakit, segera beri tahu dokter Anda. Anda harus berhenti menyusui jika kondisi ini terjadi.

12. Apakah pasien diizinkan mengemudi dan mengoperasikan mesin saat menggunakan obat ini?
Belum ada studi yang dilakukan untuk menentukan efek linkomisin terhadap kemampuan mengemudi dan mengoperasikan mesin.

13. Apa saja potensi efek yang tidak diinginkan dari penggunaan obat ini
Seperti semua obat-obatan yang ada, obat ini bisa menimbulkan efek samping, meskipun tidak semua orang mengalaminya.

Segera beri tahu dokter jika Anda mengalami:
- diare berat yang berkepanjangan, atau berdarah
- tanda-tanda reaksi alergi berat seperti mengi yang tiba-tiba, kesulitan bernapas, pusing, pembengkakan kelopak mata atau wajah atau bibir atau tenggorok atau lidah, atau ruam, atau gatal (khususnya yang dialami seluruh tubuh).
- melepuh dan mengelupasnya area kulit yang luas, demam, batuk, merasa tidak enak badan, dan pembengkakan gusi, lidah, atau bibir.
- menguningnya kulit dan bagian putih pada mata (sakit kuning).
- Ruam kulit yang berpotensi mengancam jiwa:
  - ruam yang meluas disertai melepuh dan mengelupasnya area kulit yang luas, khususnya di sekitar mulut, hidung, mata, atau kelamin, yang dikenal dengan nama sindrom Stevens-Johnson, atau dalam bentuk yang lebih berat disertai dengan pengelupasan kulit yang luas (lebih dari 30% permukaan tubuh) yang dikenal dengan nama *nekrolisis epidermal toksik*,
  - erupsi kulit langka yang ditandai dengan kemunculan cepat area kemerahan pada kulit disertai pustula kecil (lepuh kecil berisi cairan putih/kuning) (Pustulosis Eksantematosa Generalisata Akut, AGEP)
  - ruam kulit, yang dapat melepuh, dan terlihat menyerupai target kecil (titik gelap di tengah yang dikelilingi oleh area yang lebih pucat, dengan cincin gelap mengelilinginya - *eritema multiformis*)
  - ruam kulit merah yang meluas dengan lepuh-lepuh kecil berisi nanah (*dermatitis eksfoliatif bulosa*)

Efek samping lainnya yang mungkin antara lain:
- peradangan lidah atau mulut

- peradangan usus halus dan usus besar
- gatal-gatal
- limbah nitrogen dalam darah, produksi urine yang sangat kecil dan atau akibat insufisiensi ginjal
- diare
- mual
- muntah
- infeksi di dalam dan di sekitar vagina
- ruam, ditandai dengan area merah yang rata pada kulit yang ditutupi dengan bentol-bentol kecil, urtikaria
- peradangan usus besar yang dapat menyebabkan nyeri abdomen, demam, atau diare akibat infeksi yang disebabkan oleh *Clostridium difficile*.
- efek pada sistem darah Anda: penurunan jumlah sel darah yang dapat menyebabkan lebam atau perdarahan atau melemahnya sistem kekebalan tubuh
- pembengkakan yang terjadi tepat di bawah permukaan kulit atau membran mukosa
- penyakit serum
- henti jantung-pernapasan
- peradangan esofagus
- nyeri pada perut/abdomen
- tes fungsi hati abnormal (fungsi hati rendah)

Beri tahu dokter atau perawat Anda jika teramati adanya efek samping yang tercantum di atas.

Melaporkan efek samping
Jika Anda mengalami efek samping apa pun, konsultasikan dengan dokter, apoteker, atau perawat Anda. Termasuk setiap kemungkinan efek samping yang tidak tercantum dalam leaflet ini. Dengan melaporkan efek samping, Anda bisa membantu memberikan informasi lebih lanjut mengenai keamanan obat ini.

14. Tanda-tanda dan gejala-gejala overdosis
Efek samping apa pun dapat terjadi.

15. Apa yang harus dilakukan jika Anda menggunakan lebih dari dosis yang dianjurkan?
Jika Anda tanpa sengaja meminum terlalu banyak Kapsul Lincocin®, segera hubungi dokter Anda atau datangi unit gawat darurat di rumah sakit terdekat. Bawa selalu kemasan obat berlabel, baik yang masih ada Kapsul Lincocin® tersisa di dalamnya atau tidak. Jangan meminum kapsul lagi hingga dokter Anda memerintahkan Anda.

16. Bagaimana cara menyimpan obat ini?
Jauhkan obat ini dari pandangan dan jangkauan anak-anak.

Jangan gunakan obat ini setelah melewati tanggal kedaluwarsa yang tertera pada wadahnya.

Simpan pada suhu di bawah 30 °C.

17. Petunjuk penggunaan

Lincocin® dapat diminum sesudah atau sebelum makan. Telan tablet menggunakan cairan (misalnya segelas air). Bila memungkinkan, minum dosis harian Anda pada waktu yang sama setiap hari, misalnya pada waktu sarapan.

18. Nomor otorisasi pemasaran
Lincocin® 500 mg: Dus berisi 3 blister @ 10 kapsul, No. Reg.: DKL7219808601A1

19. Nama dan alamat pemohon dan/atau pemilik obat sesuai dengan ketentuan yang berlaku
Diproduksi oleh:
PT. Pfizer Indonesia,
Jakarta, Indonesia

20. Tanggal revisi
02/2023

21. Peringatan khusus
HARUS DENGAN RESEP DOKTER

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi.