

CINDA-MAS

Clindamycin Injection USP 150mg/ml

Read this leaflet carefully before using this medicine. - Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others; it may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Clindamycin is and what it is used for

Pharmacotherapeutic group: 1.1.11 Anti-infective medicines. Antibacterials. Other antibacterials

Clindamycin is an antibiotic used to treat infections caused by bacteria. Clindamycin kills bacteria and can be used to treat infections in various parts of the body.

Clindamycin is indicated for the treatment of the following infections caused by susceptible bacteria:

- Upper respiratory tract infections, including tonsillitis, pharyngitis, sinusitis, otitis media, and scarlet fever.
- Lower respiratory tract infections, including bronchitis, pneumonia, empyema, and lung abscess.
- Skin and soft tissue infections, including acne, boils, cellulitis, impetigo, abscesses, and infected wounds. A satisfactory response to Clindamycin therapy is expected in specific skin and soft tissue infections, such as erysipelas and paronychia (whitlow).
- Bone or joint infections, including osteomyelitis and septic arthritis. -Gynecological infections, including endometritis, cellulitis, vaginal infections, tubo-ovarian abscesses, salpingitis, and pelvic inflammatory disease, when administered concomitantly with an antibiotic covering Gram-negative aerobes. In cases of "Chlamydia trachomatis" cervicitis, monotherapy with clindamycin has proven effective in eradicating the microorganism.

-Intra-abdominal infections, including peritonitis and abdominal abscesses, when administered concomitantly with an antibiotic covering Gram-negative aerobes.

-Septicemia and endocarditis. Clindamycin's efficacy has been established in specific cases of endocarditis where the drug demonstrated a bactericidal effect against the infecting microorganism in "in vitro" susceptibility tests performed at the required serum concentrations.

-Dental infections, such as periodontal abscesses and periodontitis.

-"Plasmodium falciparum" infections: data from uncontrolled studies using various clindamycin dosages suggest it is a viable therapeutic alternative—administered either alone or in combination with quinine or amodiaquine, via oral or parenteral routes at a dose of 20 mg/kg/day for a minimum of 5 days—for treating multi-drug-resistant "Plasmodium falciparum" infection.

2. Before using Clindamycin

Do not use Clindamycin:

- if you are allergic (hypersensitive) to the active substance clindamycin, to lincocmycin, or to any of the ingredients of Clindamycin.

Take special care with Clindamycin:

- if you have a history of gastrointestinal disease, particularly colitis.
- if you have meningitis, because clindamycin does not diffuse into the cerebrospinal fluid.
- if you have an atopic condition.

- Use of Clindamycin may cause superinfections by non-susceptible microorganisms, particularly yeasts.

- In certain patients, use of this medicine may—as happens with other antibiotics—lead to severe, sometimes fatal, colitis. The onset of antibiotic-associated colitis may occur during administration of the antibiotic or 2 to 3 weeks afterwards.

If you are prescribed long-term therapy, your doctor may recommend that you undergo liver and kidney function tests.

Using Clindamycin with other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is important because there are some medicines that cannot be taken together with Clindamycin.

In particular, tell your doctor if you are taking:

- Erythromycin, because antagonism "in vitro" has been demonstrated between Clindamycin and Erythromycin.
- Neuromuscular blocking agents, because clindamycin exhibits neuromuscular blocking properties, enhancing the action of other such agents.
- Ampicillin, diphenylhydantoin sodium, barbiturates, aminophylline, calcium gluconate, and magnesium sulfate, because they are physically incompatible with clindamycin phosphate.

Pregnancy and breastfeeding

Consult your doctor or pharmacist before taking any medicine.

- Safety regarding use during pregnancy has not yet been established. -Do not take Clindamycin while breastfeeding, as clindamycin is excreted in human milk at concentrations of 0.7 to 3.8 µg/mL.

Driving and using machines

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

Important information about some components of Clindamycin

This medicine contains 36 µL of benzyl alcohol (9 µL per mL) per 4 mL ampoule. It must not be administered to premature babies or newborns. It may cause toxic reactions and allergic reactions in children up to 3 years of age.

This medicine contains 1.87 – 2.01 mmol (or 43.09 – 46.25 mg) of sodium per 4 mL ampoule. This information should be taken into account for patients on a controlled sodium diet.

3. How to use Clindamycin

Always use Clindamycin exactly as instructed by your doctor. Talk to your doctor or pharmacist if you have any questions.

Clindamycin will usually be administered by a doctor or nurse: - Intravenous administration

- Intramuscular administration

Your doctor will decide the dose to be administered. The dosage and method of administration will be determined based on the severity of the infection, the patient's condition, and the susceptibility of the microorganism involved.

Recommended dose of clindamycin phosphate (IM or IV administration): Adults:

- The usual daily adult dose of clindamycin phosphate for intra-abdominal infections, female pelvic infections, and other serious or complicated infections is 2400–2700 mg, administered in 2, 3, or 4 equal doses.
- Less complicated infections caused by susceptible microorganisms respond to lower doses in the range of 1200–1800 mg/day, administered in 3 or 4 equal doses.
- Daily doses of up to 4800 mg have been used successfully.
- IM administration of doses exceeding 600 mg is not recommended.

Children:

- Clindamycin should not be administered to premature infants or newborns.
- Children over 1 month of age: 20 to 40 mg/kg/day is recommended, in 3 or 4 equal doses.

In cases of beta-hemolytic "Streptococcus" infections, treatment should be continued for at least 10 days.

Treatment of Pelvic Inflammatory Disease and "Chlamydia trachomatis" Cervical Infections:

1. Pelvic Inflammatory Disease – inpatient treatment

Administer 900 mg of clindamycin phosphate (IV) daily, every 8 hours, concomitantly with an intravenous antibiotic with an appropriate spectrum for Gram-negative aerobes; e.g., 2.0 mg/kg of gentamicin followed by a daily dose of 1.5 mg/kg every 8 hours in patients with normal renal function. Continue with oral administration of 450 mg of clindamycin hydrochloride every 6 hours to complete a total of 10–14 days of therapy.

2. "Chlamydia trachomatis" cervicitis:

Administer 450 mg of clindamycin hydrochloride, 4 times daily, for 10–14 days.

No dosage adjustment is necessary for patients with renal impairment.

In patients with moderate to severe hepatic disease, an increase in the clindamycin half-life was observed; however, a pharmacokinetic study demonstrated that when administered every 8 hours, clindamycin accumulation is unlikely to occur. Therefore, dosage reduction is not considered necessary in cases of hepatic disease.

If you use more Clindamycin than you should

If you think you have given an excessively high dose of clindamycin, speak to your doctor immediately.

If you forget to use Clindamycin

If you think you have missed a dose, speak to your doctor or nurse.

Do not take a double dose to make up for a missed dose.

If you stop using Clindamycin: It is important that this medication be used as prescribed; treatment should not be stopped simply because you feel well again. If treatment is stopped too early, the infection may return.

Speak to your doctor if you do not feel well at the end of the prescribed treatment, or if you feel worse during treatment.

If you have any further questions about the use of this medicine, speak to your doctor or pharmacist.

4. Possible side effects

Like all medicines, Clindamycin can cause side effects, although not everyone experiences them.

Gastrointestinal: abdominal pain, nausea, vomiting, and diarrhea.

Hypersensitivity reactions: maculopapular rash and urticaria have occasionally been observed during therapy. The most frequently reported adverse reactions are mild to moderate morbilliform-type rashes. Rare cases of morbilliform erythema resembling Stevens-Johnson syndrome have been associated with clindamycin administration. Rare instances of allergic reactions have been reported.

Liver: Jaundice and abnormal liver function test results have occasionally been observed during clindamycin therapy.

Skin and mucous membranes: Pruritus, vaginitis, and, less frequently, exfoliative and vesiculobullous dermatitis.

Hematopoietic: Transient neutropenia (leukopenia), eosinophilia, agranulocytosis, and thrombocytopenia have been reported. In none of the reported cases was it possible to attribute a cause directly related to clindamycin therapy.

Cardiovascular: Rare cases of cardiorespiratory arrest and hypotension have been reported following rapid intravenous administration. Local reactions: Local irritation, pain, and abscess formation have been reported with IM injection. Thrombophlebitis has been reported following intravenous injection. These reactions can be minimized by deep IM injection and by avoiding the use of indwelling intravenous catheters.

If any of the side effects worsen, or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store Clindamycin

Store below 25°C.

Exposure to low temperatures may cause crystal formation in the solution. To dissolve them, warm the ampoule by rolling it between your hands or placing it in a water bath. Ensure that all crystals have dissolved into the solution.

Keep out of the reach and sight of children.

Do not use Clindamycin after the expiry date printed on the label after "EXP.". The expiry date refers to the last day of the month indicated. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer need. These measures will help protect the environment.

6. Other information

What Clindamycin contains:

- The active substance is clindamycin, in the form of clindamycin phosphate. Each ampoule of Clindamycin contains 300 mg of clindamycin in 2 mL of solution for injection.

The following information is intended for doctors and healthcare professionals only:

Instructions for use and handling

Dilution and Infusion

The concentration of Clindamycin in the solution prepared for infusion must not exceed 12 mg/mL. The infusion rate must not exceed 30 mg/minute. Usual dilution and infusion regimens: Dose | Diluent | Time | 300 mg | 50 mL | 10 min. | 600 mg | 50 mL | 20 min. | 900 mg | 100 mL | 30 min. | 1200 mg | 100 mL | 40 min. Administration of more than 1200 mg in a single 1-hour infusion is not recommended. Clindamycin must not be administered undiluted by intravenous bolus injection; instead, it should be administered via infusion over a minimum of 10–60 minutes.

Appropriate treatment for mild antibiotic-associated colitis

- Clindamycin therapy must be discontinued immediately.
- Treatment with colestipol or cholestyramine may be initiated.
- Colestipol and cholestyramine have proven effective in treating antibiotic-associated colitis; they should be administered at intervals separate from other concurrent therapies.
- The recommended doses for colestipol and cholestyramine are 5 g and 4 g, respectively, three times daily.

Appropriate treatment for severe antibiotic-associated colitis

- In moderate to severe cases, appropriate supportive measures—such as the administration of fluids, electrolytes, and proteins—must be initiated immediately.
- Vancomycin has proven effective in treating "Clostridium difficile"-associated colitis. The usual adult dose is 125 to 500 mg of vancomycin orally every 6 hours for 7 to 10 days. Relapses may occur following vancomycin treatment.
- Cholestyramine and colestipol can act as vancomycin sequestrants; it is advisable to observe a time interval between the administration of the two drugs.
- Oral bacitracin, administered at a dose of 25,000 U every 6 hours for 7 to 10 days, is an alternative therapy. Antiperistaltic drugs, such as opiates, diphenoxylate, or atropine, should not be prescribed.

Compatibility and Stability

The following drugs are physically incompatible with clindamycin phosphate: ampicillin, phenytoin sodium, barbiturates, aminophylline, calcium gluconate, and magnesium sulfate. Clindamycin is physically and chemically compatible for a minimum of 24 hours in 5% dextrose and normal saline injection solutions containing the following antibiotics at usual administration concentrations: amikacin sulfate, aztreonam, cefamandole nafate, cefazolin sodium, cefotaxime sodium, cefoxitin sodium, ceftazidime sodium, ceftizoxime sodium, gentamicin sulfate, netilmicin sulfate, piperacillin, and tobramycin.

The compatibility and stability of drugs added to the solution vary depending on their concentration and other conditions.

Physicochemical stability of diluted clindamycin solutions

Room temperature: Solutions containing 6, 9, and 12 mg/mL of clindamycin base in 5% dextrose in water, 0.9% sodium chloride, or Ringer's lactate in plastic vials or minibags demonstrated physical and chemical stability for at least 16 days at 25°C. Refrigeration: Solutions containing 6, 9, and 12 mg/mL of clindamycin base in 5% dextrose in water, 0.9% sodium chloride, or Ringer's lactate in plastic vials or minibags demonstrated physical and chemical stability for at least 32 days at 4°C. Freezing: Solutions containing 6, 9, and 12 mg/mL of clindamycin base in 5% dextrose in water, 0.9% sodium chloride, or Ringer's lactate in plastic vials or minibags demonstrated physical and chemical stability for at least eight weeks at -10°C.

Manufactured in India:

