Information For the User Clindamycin (300mg) Clinzadin 300 Injection

Clindamycin (300mg) Injection

Composition

Each vial contains:

 Clindamycin (as Clindamycin Phosphate) – 300 mg

Excipients:

• Sodium chloride, water for injection, and other suitable excipients.

Description

Clindamycin is a lincosamide antibiotic that inhibits bacterial protein synthesis by binding to the bacterial ribosome. It is effective against a wide range of Gram-positive aerobic and anaerobic bacteria, including certain strains of Staphylococcus and Streptococcus, as well as anaerobic infections. It is used in the treatment of severe infections requiring intravenous administration.

Indications

Clindamycin 300 mg injection is used for the treatment of serious bacterial infections, including:

- Skin and soft tissue infections
- Bone and joint infections (osteomyelitis)
- Respiratory tract infections (e.g., pneumonia, lung abscess)
- Intra-abdominal infections
- Pelvic infections (e.g., pelvic inflammatory disease, endometritis)
- Severe infections caused by anaerobic organisms
- Infective endocarditis prophylaxis in patients with specific risk factors

• Toxoplasmosis and malaria in combination with other agents

Dosage and Administration

- Adults:
 - The usual dose is 300 mg to 600 mg every 6 to 8 hours by intravenous infusion or slow injection.
 - In serious infections, the dose may be increased up to 900 mg every 6-8 hours.
 - Maximum dose: 2.7 g per day.
- Pediatric patients:
 - For children, the dose depends on the severity of the infection, ranging from 10 to 40 mg/kg/day, divided into 3-4 doses.
 - The dose for severe infections may go up to 40 mg/kg/day.
- **Renal or Hepatic Impairment:**
 - Adjustments may be necessary, especially for patients with liver dysfunction, as clindamycin is metabolized by the liver.

Administration:

- Intravenous (IV) Infusion: Dilute the required dose of Clindamycin 300 mg injection in an appropriate volume of diluent (e.g., sterile water for injection, normal saline) and infuse over 30-60 minutes.
- Intravenous Push: For smaller doses, Clindamycin may be administered as a slow IV push, but it should not exceed 10 mg per minute.

Mechanism of Action

Clindamycin binds to the 50S ribosomal subunit of bacteria, inhibiting bacterial protein synthesis, thus preventing bacterial cell growth. It is bacteriostatic at lower concentrations and bactericidal at higher concentrations, depending on the organism.

Warnings and Precautions

- Clostridium difficile-associated Diarrhea (CDAD): Antibiotic use can lead to overgrowth of Clostridium difficile, causing potentially severe or fatal diarrhea. Monitor for signs of gastrointestinal distress, including diarrhea.
- Hepatic Impairment: Use with caution in patients with liver disease as the drug is metabolized in the liver.
- Renal Impairment: Use cautiously in patients with renal dysfunction, as drug clearance may be affected.
- Hypersensitivity Reactions: Serious allergic reactions, including anaphylaxis, can occur. Immediate discontinuation of the drug is necessary if such reactions occur.
- Superinfections: Prolonged use of antibiotics, including Clindamycin, may lead to the growth of non-susceptible organisms, including fungi.

Side Effects

Common side effects may include:

- Gastrointestinal: nausea, vomiting, diarrhea, abdominal pain
- Rash
- Pain at the injection site
- Phlebitis (inflammation of the vein at the injection site)

Serious but rare side effects include:

- Clostridium difficile-associated diarrhea (CDAD)
- Severe allergic reactions: anaphylaxis, angioedema, difficulty breathing
- Liver toxicity: jaundice, dark urine, and liver failure
- Blood dyscrasias: e.g., leukopenia, thrombocytopenia, eosinophilia
- Stevens-Johnson syndrome (a rare but serious skin reaction)

Drug Interactions

- Erythromycin: May reduce the effectiveness of clindamycin when used concurrently.
- Neuromuscular blocking agents: Clindamycin may enhance the effects of neuromuscular blocking agents, leading to respiratory depression.
- Cimetidine: May increase the levels of clindamycin in the blood, increasing the risk of side effects.
- Cyclosporine: Co-administration can increase the serum concentration of cyclosporine.

Storage

- Store the vials at 15° C to 25° C (59° F to 77° F).
- Protect from light and moisture.
- Do not freeze.
- Once diluted for infusion, use the solution within 24 hours if stored at room temperature, or within 48 hours if refrigerated.

Note: Always follow the prescribed dosage and consult a healthcare professional if you experience any unusual symptoms or side effects.

Manufactured in India for:

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