CHLORAMPHENICOL

PEDIACHLOR®

125 mg/5 mL Suspension

Antibacterial

DESCRIPTION
PEDIACHLOR® is Pediatrica's brand of Chloramphenicol Palmitate, found to possess marked antimicrobial effectiveness against gram-positive and gram-negative bacteria, including large viruses and rickettsiae.

PHARMACOKINETICS
PEDIACHLOR® is rapidly absorbed from the gastrointestinal tract. Significant plasma levels of the metabolically active form are obtained within 30 minutes after ingestion. Peak plasma levels are reached in about 2 hours and disappear within 12 to 18 hours. About 60% of **PEDIACHLOR®** is bound by plasma albumin. Since **PEDIACHLOR®** is absorbed completely, stool concentration is very low. This may explain the clinical observation that Chloramphenicol in **PEDIACHLOR®** is less likely to cause diarrhea than any of the less absorbed antimicrobial agents.

Highest concentrations of **PEDIACHLOR®** are found in the kidney and liver, and lowest concentrations are found in the brain and cerebrospinal fluid. Most of the drug is excreted in urine in the inactive form.

THERAPEUTIC ACTION
PEDIACHLOR® acts on the 50-S ribosomal sub-units of bacteria and interferes with protein synthesis. It is usually bacteriostatic in action but may be bactericidal in high concentrations against highly susceptible organisms.

PEDIACHLOR® also appears to inhibit protein synthesis in rapidly proliferating mammalian cells.

FORMULATION
Each 5 mL (1 tsp) contains:
Chloramphenicol (as the Palmitate)..... 125 mg

DOSAGE
Every 6 hours.
Premature and full term infants less than 2 weeks: ..... 25 mg/kg BW/day
Full term infants over 2 weeks: ..... 50 mg/kg BW/day
Below 6 months ..... 1.25 - 2.5mL (1/4-1/2 tsp)
6 to 12 months ..... 2.5 - 5 mL (1/2 - 1 tsp)
1 to 3 years ..... 5 - 7.5mL (1-1 1/2 tsp)
3 to 6 years ..... 7.5 - 10mL (1 1/2 - 2 tsp)
6 to 12 years ..... 10 - 15mL (2-3 tsp)
Or as prescribed by the physician.

INDICATIONS
For typhoid fever caused by susceptible *S. typhi*; meningeal infections caused by *H. influenzae*; serious infections caused by susceptible strains of Salmonella, Rickettsiae, or Chlamydia; bacteremia, meningitis or other serious infections caused by aerobic and anaerobic gram negative bacteria which are resistant to all other appropriate anti-infective agents; and cystic fibrosis.

CONTRAINDICATIONS
Should not be given to patients with history of previous hypersensitivity and/or toxic reaction to Chloramphenicol. It must not be used in the treatment of trivial infections or where it is not indicated, as in colds, influenzae or infections of the throat where other antibiotics are effective; nor should it be used prophylactically to prevent bacterial infection.

WARNING
Serious and fatal blood dyscrasias (aplastic anemia, hypoplastic anemia, thrombocytopenia, and granulocytopenia) are known to occur during or following both short-term and prolonged therapy with Chloramphenicol. There have been reports of aplastic anemia which later terminated in leukemia. It is essential that adequate blood studies be made during treatment.

PRECAUTIONS
Repeated courses and prolonged treatment of the drug should be avoided. Because of the risk of the "gray syndrome", newborn infants should never be given Chloramphenicol, unless it may be lifesaving and there is no alternative treatment. Use with caution in impaired renal and hepatic function. Avoid concomitant administration with other drugs liable to depress bone marrow function.

CAUTION
Foods, Drugs, Devices, and Cosmetics Acts prohibits dispensing without prescription.

AVAILABILITY
Available in bottle of 60 mL.

STORE AT TEMPERATURES NOT EXCEEDING 30°C.

SHAKE WELL BEFORE USING.

Trusted Quality Healthcare

Manufactured by AMHERST LABORATORIES, INC.
UNILAB Pharma Campus, Barangay Mamplasan
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for **UNILAB, Inc.**
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