CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number  64-081

FINAL PRINTED LABELING
mammals at doses in excess of 100 times the human therapeutic dose. The maximum plasma half-life in humans is approximately 3-4 hours and 24 hours in animals. The excretion of penicillin G is primarily renal.

Microorganisms: In vitro tests demonstrate that penicillin G is effective against a wide range of bacterial species, including gram-positive and gram-negative bacteria. However, resistance to penicillin G can occur in some bacterial species.

Dosage and Administration: Penicillin G injections should be administered parenterally. The dosage and duration of treatment should be determined by the patient's condition and the desired therapeutic response. Generally, adult patients requiring antibiotic therapy are given 500 to 2000 mg every 6 to 8 hours, intravenously.

Contraindications: Penicillin G is contraindicated in individuals with a history of penicillin allergy or penicillin hypersensitivity. It is also contraindicated in individuals with a history of severe anaphylactic reactions to penicillin or cephalosporins.

Precautions: Patients should be monitored for anaphylactic reactions. Serum benzylpenicillin levels should be monitored in neonates and children. Benzylpenicillin should be used with caution in patients with renal impairment.

Other Adverse Effects: Penicillin G can cause a variety of side effects, including allergic reactions, gastrointestinal disturbances, and hematologic reactions. Anaphylactic reactions and anaphylactic shock are rare but serious complications of penicillin G therapy.

References: This summary is based on the information provided in the package insert of penicillin G injections. Additional information can be found in the literature on antimicrobial therapy and penicillin G.

*Note: This information is for educational purposes only and should not be used as a substitute for professional medical advice.*
APPROPRIATE CLINICAL USES

1. Salmonella typhimurium (group A & B, non-pneumonia strains)
2. Staphylococcus aureus and S. pyogenes (group A & B, non-pneumonia strains)

APPROPRIATE CLINICAL USES should be performed to determine susceptibility of the causative organism to the drug.

ADVERSE EFFECTS

1. Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including Enterococci, Clostridium difficile, and pseudomembranous colitis). Therefore, it is important to consider this diagnosis in patients who develop diarrhea or colitis associated with the use of ciprofloxacin. Such cases may range in severity from mild to life-threatening.

2. Treatment with broad-spectrum antibiotics affects the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a strain produced by Clostridium difficile is the primary cause of antibiotic-associated colitis. Most strains of pseudomembranous colitis usually respond to drug discontinuation alone. In instances in which this management should include supportive measures, rehydration and electrolyte disturbances, and fluid replacements. When the cause does not improve after the drug has been discontinued or when it is unsure that the cause is the drug of choice, other factors for antibiotic-associated pseudomembranous colitis should be ruled out.

PRECAUTIONS

1. An allergic reaction to ciprofloxacin occurs. The drug should be discontinued and, if necessary, an alternate drug should be treated with an alternate agent, e.g., ampicillin or sulbactam.

2. Prolonged use of ciprofloxacin may result in the development of resistant organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, an appropriate measure should be taken.

Passive does of Colmani have been reported during treatment with the drug. Administration of a single dose of Colmani to a pregnant woman is not recommended. The safety and efficacy of Colmani in pregnant women have not been established.

Adverse reactions have been reported in about 1% of patients and include gastrointestinal disturbances (1 in 100). Flushing, urticaria, and positive Coombs tests each occur in less than 1 in 200 patients.

Some of these adverse reactions have been reported with the use of intravenous immunoglobulin (IVIG) in other patients. IVIG-related reactions include fever, chills, and other skin manifestations. Adverse events associated with intravenous immunoglobulin therapy include fever, chills, and other symptoms. These adverse events are generally mild to moderate in severity and occur in less than 1% of patients. Serious adverse events such as anaphylaxis, hypotension, and anaphylactoid reactions have not been reported in clinical trials of IVIG. Severe adverse events such as respiratory distress, circulatory collapse, and cardiovascular collapse have been reported in clinical trials of IVIG.

The use of IVIG during pregnancy may be associated with an increased risk of serious adverse events, including anaphylaxis and anaphylactoid reactions. However, the safety and efficacy of IVIG in pregnant women have not been established.

Adverse reactions reported during treatment with Colmani are listed below:

- Nausea, vomiting, diarrhea, and abdominal pain
- Headache, dizziness, and tinnitus
- Anaphylaxis, hypotension, and anaphylactoid reactions
- Fever, chills, myalgia, and arthralgia
- Rash, urticaria, and pruritus
- Hemolytic anemia, Coombs-positive reactions, and thrombocytopenia
- Meningitis, encephalitis, and Guillain-Barré syndrome
The symptoms, signs, and other manifestations associated with hyperthyroidism, such as weight loss, nervousness, and intolerance of heat, often occur in children. These symptoms may persist for months before the onset of the disease. A child with symptoms of hyperthyroidism should be evaluated by a physician. A physical examination should be performed, including a careful examination of the head, neck, and thyroid gland. Laboratory tests should be obtained, including a complete blood count, serum electrolyte levels, and thyroid function tests. Needle aspiration biopsy should be performed if necessary to obtain a sample of thyroid tissue for histological examination. Treatment of hyperthyroidism in children includes medical therapy and, in some cases, surgery. Medical therapy is usually the first choice of treatment, and it consists of antithyroid medications, such as methimazole or propylthiouracil. Surgery may be necessary in cases of severe hyperthyroidism or when medical therapy fails to control the symptoms. It is important to monitor the effects of treatment and adjust the dosage as needed. Regular follow-up visits with a physician are recommended to ensure effective management of hyperthyroidism in children.
Spleen and Symptomatic—The basic components lowering an increased pressure of the spleen may include severe palmar pain and tenderness, rigidity of the thoracic cage, and restriction of respiratory movements. The treatment for the symptoms associated with the effects of the disease is more important in a patient's care plan, as the relationship between symptoms may be more pronounced in a patient's care plan. The symptoms may be more pronounced in a patient's care plan.

Tests to obtain a more accurate picture of the relationship between the symptoms and signs of the disease are needed. These tests include a full blood count, BUN and electrolyte screening, and liver function tests. These tests are needed to determine the severity of the disease and to monitor the patient's response to treatment.

The symptoms of the disease may include:

- Palmar pain
- Palmar tenderness
- Rigidity of the thoracic cage

These symptoms may be more pronounced in a patient's care plan, as the relationship between symptoms may be more pronounced in a patient's care plan.