Cefoxitin is a broad-spectrum, semi-synthetic cephalosporin antibiotic that has a unique structure. It is effective against a wide range of bacteria, including those that are resistant to other antibiotics.

**Mechanism of Action**
Cefoxitin inhibits the bacterial cell wall by inhibiting peptidoglycan synthesis, a process essential for bacterial cell wall integrity. This action leads to the death of the bacterial cell.

**Pharmacokinetics**
Cefoxitin is administered intravenously and is rapidly distributed throughout the body. It has a short half-life, which means it needs to be administered at regular intervals. It is excreted mainly unchanged in the urine.

**Indications and Usage**
Cefoxitin is used to treat a variety of bacterial infections, including those caused by Gram-negative and Gram-positive bacteria. It is particularly effective against anaerobic bacteria, and it is often used in combination with other antibiotics.

**Precautions and Adverse Reactions**
Patients should be monitored for allergic reactions and other adverse effects, such as fever, rash, and gastrointestinal disturbances. Cefoxitin may also cause skin reactions, particularly in people who have had a reaction to other cephalosporins.

**Contraindications**
Cefoxitin should not be used in patients with severe hypersensitivity to cephalosporins, penicillins, or related antibiotics. It should also be used with caution in patients with renal or hepatic impairment, as it may accumulate and increase the risk of adverse effects.

**Dosage and Administration**
The dosage and administration of cefoxitin should be determined based on the patient's medical condition and the specific infection being treated. It is usually administered intravenously at doses of 2 to 6 grams per day, divided into 4 to 6 doses over 24 hours.

**Pharmaceutical Forms**
Cefoxitin is available in powder form for intravenous infusion, and as a suspension for intramuscular injection. It is also available in a fixed-dose combination with metronidazole for the treatment of certain infections.

**Interactions**
Cefoxitin may interact with other antibiotics, particularly aminoglycosides, and with antacids. It is important to inform the healthcare provider of all medications being taken to avoid potential interactions.

**Summary**
Cefoxitin is a valuable antibiotic for the treatment of a wide range of bacterial infections. It is particularly effective against anaerobic bacteria, and it is often used in combination with other antibiotics. However, it should be used with caution in patients with renal or hepatic impairment, and it may cause skin reactions in some people.
BLOOD
Eosinophilia, leukopenia including granulocytopenia, neutropenia, anemia, including hemolytic anemia, thrombocytopenia, and jaundice have been reported.

Liver Function
Transient elevations in SGOT, SGPT, serum LDH, and serum alkaline phosphatase have been reported.

Renal Function
Elevations in serum creatinine and/or blood urea nitrogen levels have been observed. As with the cephalosporins, acute renal failure has been reported rarely. The rate of clofazimine in changes in renal function tests is difficult to assess, since factors predisposing to prerenal or to impaired renal function usually have been present.

In addition to the adverse reactions listed above which have been observed in patients treated with clofazimine, the following adverse reactions and abnormal laboratory test results have been reported for cephalosporin class antibiotics:

Drugs, including clofazimine, should be used for more severe or serious infections. The total daily dosage should not exceed 10 grams in 24 hours. Resistance resulting from such debilitating conditions as malnutrition, trauma, surgery, diabetes, heart failure, or malignancy, particularly if shock is present or impending.

Non-nephrotic syndrome: a loading dose of 2 grams should be given after the loading dose has been completed and the initial volume of 400 mL has been administered. Dosage should be reduced progressively if the patient becomes oliguric or anuria develops. Anticoagulant therapy can be continued if clinically indicated.

Oversedation
The acute intravenous LD₅₀ in the adult female mouse and rabbit was about 8 g/kg and greater than 10 g/kg. The acute intravenous LD₅₀ in the adult rat was greater than 10 g/kg.

Preparation of Solution
Table 5 provides for convenient constituting clofazimine for injection for intravenous administration.

For Mice
One gram should be constituted with at least 10 mL, and 2 grams with 20 or 10 mL of sterile Water for Injection, 0.9 percent Sodium Chloride Injection, or 5 percent Dextrose Injection. These primary solutions may be further diluted in 10 or 20 mL of the diluents listed under the head of the COMPATIBILITY AND STABILITY section.

For Mice
Clofazimine for injection may be administered intravenously after constitution. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container remain unopened.

Administration
The intravenous route is preferable for patients with bacteremia, bacterial septicaemia, or other severe or life-threatening infections, or for patients who may be poor risks because of lowered resistance resulting from debilitating conditions as malnutrition, trauma, surgery, diabetes, heart failure, or malignancy, particularly if shock is present or impending.

During administration, a solution containing 1 gram or 2 grams in 10 mL of sterile Water for Injection can be injected over a period of three to five minutes. Using an injection speed of 10 mL per minute, it may also be given over a longer period of time through the tubing system by which the patient may be receiving other intravenous infusions. However, patients may be receiving other intravenous infusions. However, clofazimine and amoxicillin can be administered sequentially without the patient. (see PRECAUTIONS).

Intrathecal
For intermittent intravenous administration, a solution containing 1 gram or 2 grams in 10 mL of sterile Water for Injection can be injected over a period of three to five minutes. Using an injection speed of 10 mL per minute, it may also be given over a longer period of time through the tubing system by which the patient may be receiving other intravenous infusions. However, patients may be receiving other intravenous infusions. However, clofazimine and amoxicillin can be administered sequentially without the patient. (see PRECAUTIONS).

COMPATIBILITY AND STABILITY
Vials
Clofazimine for injection, as supplied in vials and constituted to 1 gram/10 mL with sterile Water for Injection, Bacteriostatic Water for Injection, for injection (PREPARATION OF SOLUTION), 0.9 percent Sodium Chloride Injection, or 5 percent Dextrose Injection, maintains therapeutic potency for 6 hours at room temperature or for one week under refrigeration (below 5°C).

These primary solutions may be further diluted in 50 to 1000 mL of the following diluents and maintain potency for an additional 14 hours at room temperature or an additional 48 hours under refrigeration:

0.9 percent Sodium Chloride Injection
5 percent or 10 percent Dextrose Injection
5 percent Dextrose and 0.9 percent Sodium Chloride Injection
5 percent Sodium Chloride Injection
Lactated Ringer’s Injection
5 percent Dextrose in Lactated Ringer’s Injection
5 percent Sodium Bicarbonate Injection
AM sodium lactate solution
Mannitol 5% and 10%

After the periods mentioned above, any unused solutions should be discarded.

HOW SUPPLIED
Streptococcus for injection is a dry white to off-white powder supplied in vials containing cefoxitin sodium as follows:

Each vial contains cefoxitin sodium equivalent to 1 gram or 2 grams cefoxitin.

STORAGE
The usual adult dosage range is 1 gram to 2 grams every six to eight hours. Dosage should be determined by susceptibility of the causative organisms, severity of infection, and the condition of the patient (see Table 3 for dosage guidelines).

If C. ruminantium is a suspected pathogen, appropriate anti-ruminal coverage should be advised. The clofazimine sodium has no activity against this organism.

Clofazimine for injection may be used in patients with reduced renal function with the following dosage adjustments:

In adults with renal insufficiency, an initial loading dose of 1 gram to 2 grams may be given. After a loading dose, the recommendations for maintenance dosage (Table 4) may be used as a guide.

When only the serum creatinine level is available, the following formulas (based on sex, weight, and age of the patient) may be used to convert this value into creatinine clearance. The serum creatinine should represent a steady state of renal function.

Males:

\[ \text{Creatinine clearance (mL/min)} = \frac{140 \times \text{weight (kg)}}{\text{age (years)} + 0.85 \times \text{serum creatinine (mg/dL)}} \]

Table 4 - Maintenance Dose of Cefoxitin for Injection in Adults with Reduced Renal Function

<table>
<thead>
<tr>
<th>Renal Function</th>
<th>Creatinine Clearance (mL/min)</th>
<th>Dose (mg)</th>
<th>Frequency</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild impairment</td>
<td>30 to 50</td>
<td>1 to 2</td>
<td>every 8 to 12 hours</td>
<td>IV</td>
</tr>
<tr>
<td>Moderate impairment</td>
<td>29 to 10</td>
<td>1 to 2</td>
<td>every 8 to 12 hours</td>
<td>IV</td>
</tr>
<tr>
<td>Severe impairment</td>
<td>9 to 5</td>
<td>0.5 to 1</td>
<td>every 8 to 12 hours</td>
<td>IV</td>
</tr>
<tr>
<td>Essentially no function</td>
<td>&lt;5</td>
<td>not recommended</td>
<td>not recommended</td>
<td>not recommended</td>
</tr>
</tbody>
</table>

Special storage instructions
Clofazimine for injection in the dry state should be stored between 2 to 25°C (36 to 77°F). Avoid exposure to temperatures above 50°C. The dry material as well as solutions tend to darken, depending on storage conditions; product potency, however, is not adversely affected.

CLINICAL STUDIES
A prospective, randomized, double-blind, placebo-controlled clinical trial was conducted to determine the efficacy of short-term prophylaxis with clofazimine for injection in patients undergoing orthopedic, neurosurgical procedures who were at risk for subsequent endocarditis because of ruptured native mitral valves. Patients were randomized to receive either three doses of placebo (n=23), a single dose of clofazimine for injection (50 mg) followed by two doses of placebo (n=44), or a three-dose regimen of clofazimine for injection (each dose consisting of 2.5 mg), given intravenously, usually beginning at the time of clamping of the umbilical cord, with the second and third doses given 4 and 8 hours postoperatively. Endocarditis occurred in 14 (37.5%) patients given placebo, 5/13 (38%) patients given a single dose of clofazimine for injection, and 3/15 (20%) patients given three doses of clofazimine for injection. The differences in the endocarditis rates between the two groups treated with clofazimine for injection and placebo with respect to endocarditis were statistically significant (p<0.05) in favor of clofazimine for injection. The differences between the one-dose and three-dose regimens of clofazimine for injection were not statistically significant.

Two double-blind, randomized studies compared the efficacy of a single 2 gram intravenous dose of cefoxitin for injection to a single 2 gram intravenous dose of cefoxitin in the prevention of the in-hospital sub-infection (major morbidity) and non-sub-infection (minor morbidity) in patients following cesarean section. In the first study, 80/108 (77.6%) patients treated with cefoxitin for injection and 71/88 (74.7%) patients treated with cefoxitin experienced no major or minor morbidity. The difference in the outcomes in this study (95% CI: -0.03, +0.21) was not statistically significant. In the second study, 60/74 (81.6%) patients treated with cefoxitin for injection and 62/76 (81.6%) patients treated with cefoxitin experienced no major or minor morbidity. The difference in the outcomes in this study (95% CI: -0.04, +0.16) was not statistically significant.