CEFOTAN® (cefotetan disodium for injection) and CEFOTAN® (cetotetan for injection) in GALAXY® Plastigrip container (F. Hoffmann-La Roche, Cessnock, N.S.W.) are intended for intravenous or intramuscular administration. The solution varies from clear and colorless to slightly turbid and faintly yellow in color.

CEFOTAN® is a cephalosporin antibiotic and is a prodrug of cefotetan, which is an active beta-lactam antibiotic. Cefotetan is a broad-spectrum antimicrobial agent active against Gram-positive and Gram-negative bacteria, as well as anaerobic bacteria.

CEFOTAN® is used to treat a wide range of infections caused by susceptible bacteria, including those caused by Streptococcus pneumoniae, Haemophilus influenzae, and Bacteroides species. It is also effective against anaerobic bacteria such as Peptococcus and Peptostreptococcus species.

**Pharmacology**

CEFOTAN® has a broad spectrum of activity against a wide range of pathogens. It is effective against many Gram-positive and Gram-negative bacteria, as well as anaerobic bacteria. Cefotetan is active against most strains of Streptococcus pneumoniae, Haemophilus influenzae, and Bacteroides species.

**Dosage and Administration**

CEFOTAN® should be administered by intravenous or intramuscular injection. The recommended dosage is 1 g every 8 hours for adults and 0.5 g every 8 hours for children. In some cases, the dosage may be adjusted based on the severity of the infection and the patient's condition.

**Contraindications**

CEFOTAN® is contraindicated in patients with a history of cephalosporin allergy. It should also be avoided in patients with severe renal impairment or those who are at risk of developing severe hypersensitivity reactions.

**Warnings**

CEFOTAN® should be used with caution in patients with a history of renal impairment or those at risk of developing renal toxicity. It should also be used with caution in patients with a history of gastrointestinal bleeding or those at risk of developing gastrointestinal toxicity.

**Interactions**

CEFOTAN® may interact with other medications, including antibiotics, anti-fungal agents, and anti-viral drugs. It may also interact with medications used to treat diabetes, hypertension, or gastrointestinal disorders.

**Adverse Reactions**

CEFOTAN® may cause adverse reactions, including diarrhea, nausea, vomiting, and abdominal pain. Severe reactions, such as anaphylaxis, have also been reported.

**Plastic and Polymer Container Cautions**

CEFOTAN® is packaged in a specially designed multilayer plastic (PL 2040) container. This design is intended to minimize the risk of contamination and optimize the shelf life of the medication.

**Quality Control**

The quality of CEFOTAN® is monitored through various tests, including microbiological testing and chemical analysis, to ensure that it meets the required standards of purity and potency.

**Patient Counseling**

Patients should be instructed on the correct use of CEFOTAN® and the importance of completing the full course of treatment, even if they feel better. They should also be advised to report any side effects or allergic reactions to their healthcare provider.

**Summary**

CEFOTAN® is a powerful and effective antibiotic that is widely used in the treatment of various infections. Its broad spectrum of activity makes it a valuable addition to the antibiotic armamentarium, but it should be used with caution and in conjunction with other medications as necessary.
CEFOTAN® (cefotetan disodium for injection) and CEFOTAN® (cefotetan injection)

CEFOTAN® (cefotetan disodium for injection) and CEFOTAN® (cefotetan injection) are indicated for the treatment of infections caused by susceptible bacteria (see CLINICAL PHARMACOLOGY). These indications are based on in vitro and in vivo studies. The following should also be considered:

1. Serum creatinine level should represent a steady state ofCreatinine Clearance.

2. The intravenous route is preferable for patients with bacteremia, bacterial septicemia, or other severe or life threatening infections, or for patients who may be poor risks because of surgery, diabetes, heart failure, or malignancy, particularly if sick or preterminal.

3. Preparations for Intravenous Use (See Aseptic Technique):

- Reconstitute with Sterile Water for Injection. Shake to dissolve and let stand until clear.
- Alternatively, the dosing interval may remain constant at 12 hour intervals, but the dose may be increased to 3 g every 24 hours. The dose should be increased to 6 gm/day in patients with moderate to severe renal impairment. The dose should be increased to 6 gm/day in patients with moderate to severe renal impairment.

DOSAGE GUIDELINES FOR PATIENTS WITH IMPAIRED RENAL FUNCTION

Creatinine Clearance

<table>
<thead>
<tr>
<th>Creatinine Clearance (mL/min)</th>
<th>Dose Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 or less</td>
<td>2 g every 12 hours IV or IM</td>
</tr>
<tr>
<td>11 to 19</td>
<td>2 g every 24 hours IV or IM</td>
</tr>
<tr>
<td>20 to 49</td>
<td>2 g every 48 hours IV or IM</td>
</tr>
<tr>
<td>50 or more</td>
<td>2 g every 72 hours IV or IM</td>
</tr>
</tbody>
</table>

4. In general, the dosing interval should be 12 hours, but the dose may be increased to 3 g every 24 hours. The dose should be increased to 6 gm/day in patients with moderate to severe renal impairment. The dose should be increased to 6 gm/day in patients with moderate to severe renal impairment.

5. CEFOTAN® is a dry, white to pale yellow powder that is soluble in water. After reconstitution, CEFOTAN (cefotetan disodium for injection) is a sterile, clear, colorless solution. The solution is stable for 48 hours at ambient temperature and for 7 days at refrigeration temperature (2°C-8°C) or 30 days at frozen temperature (-20°C/-4°F).

6. CEFOTAN® (cefotetan injection) in Galaxy® plastic container (PL 2040) should be given over 20 to 60 minutes. CEFOTAN® (cefotetan injection) in Galaxy® plastic container (PL 2040) should be given over 20 to 60 minutes through the sampling port by which the patient may be receiving other intravenous solutions. Butyral® or scalp vein needles are preferred. When using a scalp vein needle, be sure to advance the needle through capillary action without creating air bubbles.

7. Overdosage with CEFOTAN in humans is not available. If overdosage should occur, it should be treated symptomatically and hemodynamically considered, partial or complete evacuation of the gastrointestinal tract may be necessary. In addition, systemic symptoms may be treated symptomatically.

8. The intravenous route is preferable for patients with bacteremia, bacterial septicemia, or other severe or life threatening infections, or for patients who may be poor risks because of surgery, diabetes, heart failure, or malignancy, particularly if sick or preterminal.

9. In general, the dosing interval should be 12 hours, but the dose may be increased to 3 g every 24 hours. The dose should be increased to 6 gm/day in patients with moderate to severe renal impairment. The dose should be increased to 6 gm/day in patients with moderate to severe renal impairment.

10. The intravenous route is preferable for patients with bacteremia, bacterial septicemia, or other severe or life threatening infections, or for patients who may be poor risks because of surgery, diabetes, heart failure, or malignancy, particularly if sick or preterminal.

11. Overdosage with CEFOTAN in humans is not available. If overdosage should occur, it should be treated symptomatically and hemodynamically considered, partial or complete evacuation of the gastrointestinal tract may be necessary. In addition, systemic symptoms may be treated symptomatically.

12. The intravenous route is preferable for patients with bacteremia, bacterial septicemia, or other severe or life threatening infections, or for patients who may be poor risks because of surgery, diabetes, heart failure, or malignancy, particularly if sick or preterminal.

13. In general, the dosing interval should be 12 hours, but the dose may be increased to 3 g every 24 hours. The dose should be increased to 6 gm/day in patients with moderate to severe renal impairment. The dose should be increased to 6 gm/day in patients with moderate to severe renal impairment.

14. Overdosage with CEFOTAN in humans is not available. If overdosage should occur, it should be treated symptomatically and hemodynamically considered, partial or complete evacuation of the gastrointestinal tract may be necessary. In addition, systemic symptoms may be treated symptomatically.