ZIPRAX Dispersible Tablets / Dry Syrup (Cefixime)

**Composition**

ZIPRAX-50 DT
Each uncoated dispersible tablet contains:
Cefixime, IP, as a trihydrate equivalent to Anhydrous Cefixime ............... 50 mg
In a flavoured base

ZIPRAX-100 DT
Each uncoated dispersible tablet contains:
Cefixime, IP, as a trihydrate equivalent to Anhydrous Cefixime ...............100 mg
In a flavoured base

ZIPRAX-200 DT
Each uncoated dispersible tablet contains:
Cefixime, IP, as a trihydrate equivalent to Anhydrous Cefixime ...............200 mg
In a flavoured base

ZIPRAX-50 Dry Syrup
Each 5 ml (after reconstitution) contains:
Cefixime, IP as trihydrate equivalent to Anhydrous Cefixime ...............50 mg

ZIPRAX-100 Dry Syrup
Each 5 ml (after reconstitution) contains:
Cefixime IP as trihydrate equivalent to Anhydrous Cefixime ...............100 mg

**Dosage Forms**

Dispersible tablet and dry powder for oral suspension.

**Pharmacology**

**Pharmacodynamics**

Cefixime is a semi-synthetic, oral third-generation cephalosporin, which has marked *in vitro* bactericidal activity against a wide variety of gram-positive and gram-negative organisms. Bactericidal action of cefixime results from inhibition of cell-wall synthesis.
It is highly stable in the presence of beta-lactamase enzymes.

Most strains of Enterococci (Streptococcus faecalis, group D Streptococci) and Staphylococci (including coagulase-positive and -negative strains and methicillin-resistant strains) are resistant to cefixime. In addition, most strains of Pseudomonas, Bacteroidesfragilis, Listeria monocytogenes and Clostridia are resistant to cefixime.

Cefixime has been shown to be active against most isolates of the following bacteria both in vitro and in clinical infections:

- **Gram-positive Bacteria**
  - Streptococcus pneumoniae
  - Streptococcus pyogenes

- **Gram-negative Bacteria**
  - Haemophilus influenzae (beta-lactamase-positive and -negative)
  - Moraxella catarrhalis
  - Escherichia coli
  - Proteus mirabilis
  - Neisseria gonorrhoeae

Also, clinical efficacy has been demonstrated in infections caused by commonly occurring pathogens, including Branhamellacatarrhalis (beta-lactamase-positive and -negative) and Enterobacter species.

The following in vitro data are available, but their clinical significance is unknown. Cefixime exhibits in vitro MICs of 1 mcg/mL or less against most (≥90%) isolates of the following bacteria; however, the safety and effectiveness of cefixime in treating clinical infections due to these bacteria have not been established in adequate and well-controlled clinical trials.

- **Gram-positive Bacteria**
  - Streptococcus agalactiae

- **Gram-negative Bacteria**
  - Haemophilus parainfluenzae
  - Proteus vulgaris
  - Klebsiellapneumoniae
  - Klebsiellaoxytoca
  - Pasteurellamultocida
  - Providenciaspecies
  - Salmonella species
  - Shigellaspecies
  - Citrobacteramalonaticus
  - Citrobacterdiversus
  - Serratiamarcescens

### Pharmacokinetics

**Absorption**

The absolute oral bioavailability of cefixime is in the range of 22 to 54%. Cefixime tablets and suspension, given orally, are about 40 to 50% absorbed whether administered with or without food; however, time to maximal absorption is increased approximately 0.8 hours when administered with food. Typically, the peak serum levels following the recommended adult or paediatric doses are between 1.5 and 3 mcg/ml. A single 200 mg tablet of cefixime produces an average peak serum concentration of approximately 2 mcg/mL (range: 1 to 4 mcg/mL). The oral suspension produces average peak concentrations approximately 25 to 50% higher than the tablets, when tested in normal adult volunteers.
Oral suspension 200 mg doses produce average peak concentrations of 3 mcg/mL (range: 1 to 4.5 mcg/mL), when tested in normal adult volunteers. The area under the time versus concentration curve (AUC) is greater by approximately 10 to 25% with the oral suspension than with the tablet after doses of 100 to 400 mg, when tested in normal adult volunteers. This increased absorption should be taken into consideration if the oral suspension is to be substituted for the tablet. Because of the lack of bioequivalence, tablets should not be substituted for oral suspension in the treatment of otitis media. Crossover studies of tablet versus suspension have not been performed in children. Absorption is not significantly modified by the presence of food. Cefixime may, therefore, be given without regard to meals.

Peak serum concentrations occur between 2 and 6 hours following oral administration of a single 200 mg tablet, a single 400 mg tablet, or 400 mg of cefixime suspension. Peak serum concentrations occur between 2 and 5 hours following a single administration of 200 mg of suspension. From in vitro studies, serum or urine concentrations of 1 mcg/ml or greater were considered to be adequate for most common pathogens against which cefixime is active.

Distribution
Cefixime is almost exclusively bound to the albumin fraction, the mean free fraction being approximately 30%. Serum protein binding is concentration independent, with a bound fraction of approximately 65%. Protein binding of cefixime is only concentration-dependent in human serum at very high concentrations, which are not seen following clinical dosing. In a multiple-dose study conducted with a research formulation, which is less bioavailable than the tablet or suspension, there was little accumulation of drug in serum or urine after dosing for 14 days. Adequate data on cerebrospinal fluid (CSF) levels of cefixime are not available.

Metabolism and Excretion
There is no evidence of metabolism of cefixime in vivo. Approximately 50% of the absorbed dose is excreted unchanged in the urine in 24 hours. Glomerular filtration is considered the predominant mechanism. Metabolites of cefixime have not been isolated from human serum or urine. In animal studies, it was noted that cefixime is also excreted in the bile in excess of 10% of the administered dose. The serum half-life of cefixime in healthy subjects is independent of dosage form and averages 3 to 4 hours, but may range up to 9 hours in some normal volunteers.

Special Populations
Geriatrics
Average AUCs at steady state in elderly patients are approximately 40% higher than average AUCs in other healthy adults. Differences in the pharmacokinetic parameters between 12 young and 12 elderly subjects who received 400 mg of cefixime once daily for 5 days are summarized as follows:

<table>
<thead>
<tr>
<th>Pharmacokinetic parameter</th>
<th>Young</th>
<th>Elderly</th>
</tr>
</thead>
<tbody>
<tr>
<td>C&lt;sub&gt;max&lt;/sub&gt; (mg/L)</td>
<td>4.74 ± 1.43</td>
<td>5.68 ± 1.83</td>
</tr>
<tr>
<td>T&lt;sub&gt;max&lt;/sub&gt; (h)*</td>
<td>3.9 ± 0.3</td>
<td>4.3 ± 0.6</td>
</tr>
<tr>
<td>AUC (mg.h/L)*</td>
<td>34.9 ± 12.2</td>
<td>49.5 ± 19.1</td>
</tr>
<tr>
<td>T&lt;sub&gt;1/2&lt;/sub&gt; (h)*</td>
<td>3.5 ± 0.6</td>
<td>4.2 ± 0.4</td>
</tr>
<tr>
<td>C&lt;sub&gt;ave&lt;/sub&gt; (mg/L)*</td>
<td>1.42 ± 0.50</td>
<td>1.99 ± 0.75</td>
</tr>
</tbody>
</table>

* Difference between age groups was significant. (p<0.05)
However, these increases were not clinically significant.
**Renal Impairment**

In subjects with moderate impairment of renal function (20 to 40 mL/min creatinine clearance), the average serum half-life of cefixime is prolonged to 6.4 hours. In severe renal impairment (5 to 20 mL/min creatinine clearance), the half-life increased to an average of 11.5 hours. The drug is not cleared significantly from the blood by haemodialysis or peritoneal dialysis. However, a study indicated that with doses of 400 mg, patients undergoing haemodialysis have similar blood profiles as subjects with creatinine clearances of 21 to 60 mL/min.

**Indications**

To reduce the development of drug-resistant bacteria and maintain the effectiveness of cefixime and other antibacterial drugs, cefixime should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.

When culture and susceptibility information are available, they should be considered in selecting or modifying antimicrobial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

ZIPRAX DT/Dry Syrup is indicated in the treatment of adults and paediatric patients, 6 months of age or older, with the following infections when caused by susceptible isolates of the designated bacteria:

- **Uncomplicated Urinary Tract Infections** (e.g. cystitis, cystourethritis, uncomplicated pyelonephritis) caused by *Escherichia coli* and *Proteus mirabilis*.
- **Upper Respiratory Tract Infections (URTI)** where the causative organism is known or suspected to be resistant to other commonly used antibiotics, or where treatment failure may carry significant risk.
- **Otitis Media** caused by *Haemophilus influenzae*, *Moraxella catarrhalis*, and *Streptococcus pyogenes*.

(Efficacy for *Streptococcus pyogenes* in this organ system was studied in fewer than 10 infections).

Note: For patients with otitis media caused by *Streptococcus pneumoniae*, overall response was approximately 10% lower for cefixime than for the comparator.

- **Pharyngitis and Tonsillitis** caused by *Streptococcus pyogenes*.
  
  Note: Penicillin is the usual drug of choice in the treatment of *Streptococcus pyogenes* infections. Cefixime is generally effective in the eradication of *Streptococcus pyogenes* from the nasopharynx; however, data establishing the efficacy of cefixime in the subsequent prevention of rheumatic fever is not available.

- **Acute Exacerbations of Chronic Bronchitis** caused by *Streptococcus pneumoniae* and *Haemophilus influenzae*.

- **Uncomplicated Gonorrhoea** (cervical/urethral) caused by *Neisseria gonorrhoeae* (penicillinase-and non-penicillinase-producing isolates).

**Dosage And Administration**

**Dosage**

The usual course of treatment is 7 days. This may be continued for up to 14 days if required.

**Adults**

The recommended dosage is 200-400 mg daily according to the severity of infection, given either as a single dose or in two divided doses.

For the treatment of uncomplicated cervical/urethral gonococcal infections, a single oral dose of 400 mg is recommended.

In the treatment of infections due to *Streptococcus pyogenes*, a therapeutic dosage of cefixime should be administered for at least 10 days.

**Paediatric Patients (Aged 6 Months or Older)**
The recommended dose is 8 mg/kg/day of the suspension. This may be administered as a single daily dose or may be given in two divided doses, as 4 mg/kg every 12 hours. A suggested dose has been determined for each paediatric weight range in Table 1.

Table 1: Suggested doses for paediatric patients

<table>
<thead>
<tr>
<th>Patient Weight (kg)</th>
<th>Dose/Day (mg)</th>
<th>Dose/Day (mL)</th>
<th>Dose/Day (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 to 7.5</td>
<td>50</td>
<td>5</td>
<td>2.5</td>
</tr>
<tr>
<td>7.6 to 10</td>
<td>80</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>10.1 to 12.5</td>
<td>100</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>12.6 to 20.5</td>
<td>150</td>
<td>15</td>
<td>7.5</td>
</tr>
<tr>
<td>20.6 to 28</td>
<td>200</td>
<td>20</td>
<td>10</td>
</tr>
<tr>
<td>28.1 to 33</td>
<td>250</td>
<td>--</td>
<td>12.5</td>
</tr>
<tr>
<td>33.1 to 40</td>
<td>300</td>
<td>--</td>
<td>15</td>
</tr>
<tr>
<td>40.1 to 45</td>
<td>350</td>
<td>--</td>
<td>17.5</td>
</tr>
<tr>
<td>45.1 or greater</td>
<td>400</td>
<td>--</td>
<td>20</td>
</tr>
</tbody>
</table>

ZIPRAX-50 Dry Syrup may be substituted with ZIPRAX-50 DT.

Children weighing more than 45 kg or older than 12 years should be treated with the recommended adult dose, 200 to 400 mg daily depending on the severity of infection.

Otitis media should be treated with suspension. Clinical trials of otitis media were conducted with the suspension, and the suspension results in higher peak blood levels than the tablet when administered at the same dose. Therefore, the tablet should not be substituted for the suspension in the treatment of otitis media.

In the treatment of infections due to *Streptococcus pyogenes*, a therapeutic dosage of cefixime should be administered for at least 10 days.

The safety and efficacy of cefixime has not been established in children less than 6 months.

_Elderly_

Elderly patients may be given the same dose as recommended for adults. Renal function should be assessed and dosage should be adjusted in severe renal impairment.

_Renal Impairment_

Cefixime may be administered in the presence of impaired renal function. Doses for patients with renal impairment is shown in the following table 2.

Table 2: Doses for Patient with Renal Impairment

<table>
<thead>
<tr>
<th>Renal Dysfunction</th>
<th>Cefixime for Oral Suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Creatinine Clearance (mL/min)</td>
<td>50 mg/5 mL</td>
</tr>
<tr>
<td>------------------------------</td>
<td>------------</td>
</tr>
<tr>
<td>Dose/Day (mL)</td>
<td>Dose/Day (mL)</td>
</tr>
<tr>
<td>60 or greater</td>
<td>Normal dose</td>
</tr>
<tr>
<td>21 to 59* OR renal hemodialysis*</td>
<td>26</td>
</tr>
<tr>
<td>20 or less OR continuous peritoneal dialysis</td>
<td>17.2</td>
</tr>
</tbody>
</table>

*The preferred concentrations of oral suspension to use are 200 mg/5 mL for patients with this renal dysfunction. In patients whose creatinine clearance is less than 20 ml/min, it is recommended that a dose of 200 mg once daily should not be exceeded. The dose and regimen for patients who are maintained on chronic ambulatory peritoneal dialysis or haemodialysis should follow the same recommendation as that for patients with creatinine clearance of less than 20 ml/min. Neither haemodialysis nor peritoneal dialysis removes significant amounts of drug from the body.

**Administration**
Absorption of ZIPRAX DT/Dry Syrup is not significantly modified by the presence of food.

**ZIPRAX DT**
Disperse the tablet in a teaspoonful (5 ml) of boiled and cooled water before administration.

**ZIPRAX Dry Syrup**

**Direction for Preparing the Suspension**
At the time of dispensing, the dry powder should be reconstituted to form an oral suspension. First, shake the bottle to loosen the powder. Twist and open the vial of sterile water given with the pack. Slowly add half quantity of the sterile water into the bottle. Recap the bottle, and shake it vigorously. Adjust the suspension volume up to the red arrow mark by adding more sterile water, if necessary, and shake again. Store the reconstituted suspension in cool place.
After reconstitution, the contents should be consumed within 7 days. Keep tightly closed. Shake well before each use. Discard the unused portion after 7 days.

### Contraindications
Cefixime is contraindicated in patients with a known allergy to cefixime or other cephalosporins or any of the other components of the product.

### Warnings And Precautions

#### General

**Hypersensitivity Reactions**
Anaphylactic/anaphylactoid reactions (including shock and fatalities) have been reported with the use of cefixime. There is some evidence of partial cross-allergenicity between the penicillins and cephalosporins. Before therapy with cefixime is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cephalosporins, penicillins or other drugs. If this product is to be given to penicillin-sensitive patients, caution should be exercised because cross-hypersensitivity among beta-lactam antibiotics has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy. If an allergic reaction to cefixime occurs, discontinue the drug.

**Severe Cutaneous Adverse Reactions**
Severe cutaneous adverse reactions such as toxic epidermal necrolysis, Stevens-Johnson syndrome and drug rash with
eosinophilia and systemic symptoms (DRESS) have been reported in some patients on cefixime. When severe cutaneous adverse reactions occur, cefixime should be discontinued and appropriate therapy and/or measures should be taken. Cefixime should be given with caution to patients who have shown hypersensitivity to other drugs.

Clostridium difficile-Associated Diarrhoea

Clostridium difficile-associated diarrhoea (CDAD) has been reported with the use of nearly all antibacterial agents, including cefixime, and may range in severity from mild diarrhoea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon, leading to overgrowth of C. difficile.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.

Studies indicate that a toxin produced by C. difficile is a primary cause of antibiotic-associated diarrhoea. Pseudomembranous colitis is associated with the use of broad-spectrum antibiotics (including macrolides, semi-synthetic penicillins, lincosamides and cephalosporins); it is, therefore, important to consider its diagnosis in patients who develop diarrhoea in association with the use of antibiotics. Symptoms of pseudomembranous colitis may occur during or after antibiotic treatment.

Management of pseudomembranous colitis should include sigmoidoscopy, appropriate bacteriologic studies, fluids, electrolytes and protein supplementation. If the colitis does not improve after the drug has been discontinued, or if the symptoms are severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by C. difficile. Other causes of colitis should be excluded.

Dose Adjustment in Renal Impairment

The dose of cefixime should be adjusted in patients with renal impairment as well as those undergoing continuous ambulatory peritoneal dialysis (CAPD) and haemodialysis (HD). Patients on dialysis should be monitored carefully.

Coagulation Effects

Cephalosporins, including cefixime, may be associated with a fall in prothrombin activity. Those at risk include patients with renal or hepatic impairment, or poor nutritional state, as well as patients receiving a protracted course of antimicrobial therapy, and patients previously stabilized on anticoagulant therapy. Prothrombin time should be monitored in patients at risk and exogenous vitamin K administered as indicated.

Haemolytic Anaemia

Drug-induced haemolytic anaemia, including severe cases with a fatal outcome, has been described for cephalosporins (as a class). The recurrence of haemolytic anaemia after re-administration of cephalosporins in a patient with a history of cephalosporin (including cefixime) -associated haemolytic anaemia has also been reported.

Renal failure acute

As with other cephalosporins, cefixime may cause acute renal failure including tubulointerstitial nephritis as an underlying pathological condition. When acute renal failure occurs, cefixime should be discontinued and appropriate therapy and/or measures should be taken.

Development of Drug-Resistant Bacteria

Prescribing cefixime in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Effects on Laboratory Tests

A false-positive reaction for ketones in the urine may occur with tests using nitroprusside, but not with those using nitroferricyanide. The administration of cefixime may result in a false-positive reaction for glucose in the urine using Benedict's solution, or Fehling's solution. It is recommended that glucose tests based on enzymatic glucose oxidase reactions be used. A false-positive direct Coombs test has been reported during treatment with other cephalosporins; therefore, it should be recognized that a positive Coombs test may be due to the drug.
Effects on ability to drive and use machines
There are no effects observed on the ability to drive and use machines

Drug Interactions

Carbamazepine
Elevated carbamazepine levels have been reported in postmarketing experience when cefixime is administered concomitantly. Drug monitoring maybe of assistance in detecting alterations in carbamazepine plasma concentrations.

Anticoagulants
In common with other cephalosporins, increases in prothrombin times with or without clinical bleeding have been noted in a few patients. Care should, therefore, be taken in patients receiving anticoagulation therapy.
Cefixime should be administered with caution to patients receiving coumarin-type anticoagulants, e.g. warfarin potassium. Since cefixime may enhance effects of the anticoagulants, prolonged prothrombin time with or without bleeding may occur.

Renal Impairment
The dose of cefixime should be adjusted in patients with renal impairment as well as those undergoing continuous ambulatory peritoneal dialysis (CAPD) and haemodialysis (HD). Patients on dialysis should be monitored carefully.

Hepatic Impairment
No data on dosing is available for patients with impaired hepatic function.

Pregnancy
Pregnancy Category B
There are no adequate and well-controlled studies in pregnant women. Cefixime should, therefore, not be used in pregnancy or in nursing mothers unless considered essential by the physician.
Cefixime has not been studied for use during labor and delivery. Treatment should only be given if clearly needed.

Lactation
It is not known whether cefixime is excreted inhuman milk. Consideration should be given to discontinuing nursing temporarily during treatment with this drug.

Paediatric Use
Safety and effectiveness of cefixime in children aged less than 6 months old have not been established. The incidence of gastrointestinal adverse reactions, including diarrhoea and loose stools, in the paediatric patients receiving the suspension, was comparable to the incidence seen in adult patients receiving tablets. No data are available in case of paediatric patients with impaired hepatic function. Please refer to DOSAGE AND ADMINISTRATION.

Geriatric Use
Clinical studies did not include sufficient numbers of subjects aged 65 and older to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. A pharmacokinetic study in the elderly detected differences in pharmacokinetic parameters. These differences were small and do not indicate a need for dosage adjustment of the drug in the elderly.

Undesirable Effects
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical
trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Cefixime is generally well tolerated. The majority of adverse reactions observed in clinical trials were mild and self-limiting in nature.

Gastrointestinal Disturbances

The most commonly seen adverse reactions were gastrointestinal events, which were reported in 30% of adult patients on either the twice-daily or the once-daily regimen. Therapy was discontinued by 5% of patients because of drug-related adverse reactions.

Individual adverse reactions included diarrhoea (16%), loose or frequent stools (6%), abdominal pain (3%), nausea (7%), dyspepsia (3%), and flatulence (4%).

Diarrhoea has been more commonly associated with higher doses. Some cases of moderate-to-severe diarrhoea have been reported; this has occasionally warranted cessation of therapy. Cefixime should be discontinued if marked diarrhoea occurs.

Other gastrointestinal side effects seen less frequently are vomiting and flatulence. Pseudomembranous colitis has been reported.

The incidence of gastrointestinal adverse reactions, including diarrhoea and loose stools, in paediatric patients receiving the suspension was comparable with the incidence seen in adult patients receiving tablets.

Central Nervous System

Headache and dizziness.

Hypersensitivity Reactions

Allergies in the form of rash, pruritus, drug fever and arthralgia have been observed, including rare cases of urticaria or angio-oedema. These reactions usually subsided upon discontinuation of therapy. Rarely, erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported.

Haematological and Clinical Chemistry

Thrombocytosis, thrombocytopenia, leucopenia, hypereosinophilia, neutropenia and agranulocytosis have been reported. These reactions were infrequent and reversible. Mild transient changes in liver and renal function tests have been observed.

Hepatic Disorders

Transient rises in liver transaminases, alkaline phosphatase and jaundice can also occur.

Miscellaneous

Other possible reactions include genital pruritus and vaginitis.

Postmarketing Experience

The following adverse reactions have been reported following the use of cefixime. Incidence rates were less than 1 in 50 (less than 2%).

Gastrointestinal

Several cases of documented pseudomembranous colitis were identified in clinical trials. The onset of pseudomembranous colitis symptoms may occur during or after therapy.

Hypersensitivity Reactions

Anaphylactic/anaphylactoid reactions (including shock and fatalities), skin rashes, urticaria, drug fever, pruritus, angio-
oedema, and facial oedema. Erythema multiforme, Stevens-Johnson syndrome, and serum sickness-like reactions have been reported.

**Hepatic**
Transient elevations in SGPT, SGOT, alkaline phosphatase, hepatitis, and jaundice.

**Renal**
Transient elevations in BUN or creatinine, acute renal failure.

**Central Nervous System**
Headaches, dizziness, seizures.

**Haemic and Lymphatic System**
Transient thrombocytopenia, leucopenia, neutropenia, prolongation in prothrombin time, elevated LDH, pancytopenia, agranulocytosis, and eosinophilia.

**Abnormal Laboratory Tests**
Hyperbilirubinaemia.

**Other Adverse Reactions**
Genital pruritus, vaginitis, candidiasis, toxic epidermal necrolysis.

**Adverse Reactions Reported for Cephalosporin-class Drugs**
Allergic reactions, superinfection, renal dysfunction, toxic nephropathy, hepatic dysfunction, including cholestasis, aplastic anaemia, haemolytic anaemia, haemorrhage, and colitis.

Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced. If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

The other undesirable effects that have been observed during clinical studies and/or during marketed use includes pyrexia, granulocytopenia, dyspnoea and increased blood bilirubin levels.

**Overdosage**

There is no experience with overdoses with cefixime. Gastric lavage may be indicated; otherwise, no specific antidote exists. Cefixime is not removed insignificant quantities from the circulation by haemodialysis or peritoneal dialysis. Adverse reactions in small numbers of healthy adult volunteers receiving single doses up to 2 g of cefixime did not differ from the profile seen in patients treated at the recommended doses. General supportive measures are recommended.

**Storage And Handling Instructions**

- **ZIPRAX DT**
  Store in a cool, dry place. Protect from light.

- **ZIPRAX Dry Syrup**

  **Before Opening**
  Store below 25°C. Protect from light.

  **After Reconstitution**
  The contents should be consumed within 7 days. Keep the bottle tightly closed. Shake well before each use. Discard the unused portion after 7 days.
Packaging Information

ZIPRAX-50: Strip pack of 10 dispersible tablets
ZIPRAX-100: Strip pack of 10 dispersible tablets
ZIPRAX-200: Strip pack of 10 dispersible tablets
ZIPRAX-50: Bottle of 30 ml dry syrup
ZIPRAX-100: Bottle of 30 ml dry syrup

Last Updated: Mar 2016
Last Reviewed: Mar 2016

ZIPRAX Dispersible Tablets / Dry Syrup

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