Supraxim®
(Cefixime)

Presentation
Supraxim® Capsule: Each capsule contains Cefixime Trihydrate USP equivalent to 200 mg Cefixime Anhydrous.
Supraxim® Powder for suspension: Each 5 ml dry suspension contains Cefixime Trihydrate USP equivalent to 100 mg Cefixime Anhydrous

Indications
Cefixime is an orally active cephalosporin antibiotic which has marked in vitro bactericidal activity against a wide variety of Gram-positive and Gram-negative organisms.
It is indicated for the treatment of the following acute infections when caused by susceptible micro-organisms:
UPPER RESPIRATORY TRACT INFECTIONS (URTI): e.g. otitis media; and other 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.
LOWER RESPIRATORY TRACT INFECTIONS: e.g. bronchitis.
URINARY TRACT INFECTIONS: e.g. cystitis, cystourethritis, uncomplicated pyelonephritis.
TYPHOID FEVER

Dosage & Administration
Absorption of Cefixime is not significantly modified by the presence of food. The usual course of treatment is 7 days. This may be continued for up to 14 days if required.
ADULTS AND CHILDREN OVER 10 YEARS: The recommended adult dosage is 200-400 mg daily according to the severity of infection, given either as a single dose or in two divided doses.
THE 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 (See "Dosage in Renal Impairment").
CHILDREN (USE PAEDIATRIC ORAL SUSPENSION): The recommended dosage for children is 8 mg/kg/day administered as a single dose or in two divided doses. As a general guide for prescribing in children the following daily doses in terms of volume of Paediatric Oral Suspension are suggested:
Children 6 months -1 year: 3.75 mL daily
Children 1-4 years: 5 mL daily
Children 5-10 years: 10 mL daily
The safety and efficacy of cefixime has not been established in children less than 6 months.

DOSAGE IN RENAL IMPAIRMENT: Cefixime may be administered in the presence of impaired renal function. Normal dose and schedule may be given in patients with creatinine clearances of 20 ml/min or greater. 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 clearances of less than 20 ml/min.

Contraindications
Patients with known hypersensitivity to cephalosporin antibiotics.

Pregnancy and Lactation
Reproduction studies have been performed in mice and rats at doses up to 400 times the human dose and have revealed no evidence of impaired fertility or harm to the foetus due to cefixime. In the rabbit, at doses up to 4 times the human dose, there was no evidence of a teratogenic effect; there was a high incidence of abortion and maternal death which is an expected consequence of the known sensitivity of rabbits to antibiotic-induced changes in the population of the microflora of the intestine.
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.

Side-Effects
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 frequent side effects seen with cefixime are diarrhoea and stool changes; 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 nausea, abdominal pain, dyspepsia, vomiting and flatulence. Pseudomembranous colitis has been reported (see above).
CENTRAL NERVOUS SYSTEM: Headache and dizziness.
HYPERSENSITIVITY REACTIONS:Allergies in the form of rash, pruritus, urticaria, drug fever and arthralgia have been observed. 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: Thrombocytopenia, leukopenia and eosinophilia 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.

Special Warnings and Precautions for use
Cefixime should be given with caution to patients who have shown hypersensitivity to other drugs. Cephalosporins should be given with caution to penicillin-sensitive patients, as there are some evidences of partial cross-allergenicity between the penicillins and cephalosporins.
Patients have had severe reactions (including anaphylaxis) to both classes of drugs. If an allergic effect occurs with Cefixime, the drug should be discontinued and the patient treated with appropriate agents if necessary.
Cefixime should be administered with caution in patients with markedly impaired renal function (See "Dosage in Renal impairment").

Interaction with Other Medicinal Products and Other Forms of Interaction
A false positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutuions or with copper sulphate test tablets, but not with tests based on enzymatic glucose oxidase reactions.
A false positive direct Coombs test has been reported during treatment with cephalosporin antibiotics, therefore it should be recognised that a positive Coombs test may be due to the drug.
In common with other cephalosporins, increases in prothrombin times have been noted in a few patients. Care should therefore be taken in patients receiving anticoagulation therapy.

Packaging Quantity
Supraxim® Capsule: 2x4's capsules in Alu-Alu Blister.
Supraxim® Powder for suspension: Amber glass bottle containing powder to prepare 30 ml suspension.
Supraxim® Powder for suspension: Amber glass bottle containing powder to prepare 50 ml suspension.

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Manufactured for :
Silva Pharmaceuticals Limited
Maijdee, Noakhali, Bangladesh
By **Pharmasia Limited**
Gojariapara, Bhawal Mirzapur, Gazipur.