SUMMARY OF PRODUCT CHARACTERISTICS(SmPC)

1. NAME OF THE MEDICINALPRODUCT

MARYICEF-200 TABLET (Cefixime tablet USP 200 Tablet)

1.1 (Trade) name of product: MARYICEF-200 TABLET

1.2 Strength

CefiximeTrihydrate USP
Eq. to Anhydrous Cefixime200 mg

1.3 Pharmaceutical Dosage Form

Tablets for oral administration

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Each uncoated Dispersable tablet contains:
CefiximeTrihydrate USP
Eq. to Anhydrous Cefixime200 mg
Excipients..... Q.S.

2.2 Quantitative Declaration

Batch Formula:

Batch Size:
100,000 Tablets

INGREDIENTS	QTY./ TABLET (IN MG)	REQ. QTY	REFERENCE
ACTIVE INGREDIENT			
Cefixime Trihydrate	228 mg	22.80	USP
INACTIVE INGREDIENTS			
MCC PH 102	39.03mg	3.903	BP
Starch USP	23.22mg	2.322	BP
LUBRICATION			
Magnesium Stearate	3.5 Mg	0.350	BP
Sodium Starch glycolate	6.0mg	0.600	BP
Talcum	4.00	0.400	BP
Aerosil	1.25	0.125	BP
Cross carmellose sodium	3.00	0.300	BP
Aspartame USP	3.500	0.350	BP
Ess. Mix Fruit dry powder	3.5	0.350	BP
Kyron T-314 Speci.	5.0	0.500	BP

3. PHARMACEUTICAL FORM

Solid Oral . White to off white round shape uncoated dispersible tablet one side break line and plain on other side of the tablet.

4. Clinical particulars

4.1 Indication

It is an orally active cephalosporin antibiotic which has marked in vitro bactericidal activity against a widevariety 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.

4.2 Posology and Administration

Posology

Adults and Children over 10 Years or weighing more than 50 kg:

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.

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.

Children under 10 Years:

Cefixime Tablets 200 mg are not recommended for use in children under 10 years old.

Renal Impairment:

Cefixime tablet 200 mg may be administered in the presence of impaired renal function. Normal dose andschedule 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 withcreatinine clearances of less than 20 ml/min.

Method for administration

For oral administration.

Absorption of cefixime tablet 200 mg is not significantly modified by the presence of food.

Contraindications

Hypersensitivity to the cephalosporin or to any of the excipients.

Special warnings and precautions foruse
Encephalopathy
Beta-lactams, including cefixime, predispose the patient to encephalopathy risk (which may include convulsions, confusion, impairment of consciousness, movement disorders), particularly in case of overdose or renal impairment.

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 tablet 200 mg should be given with caution to patients who have shown hypersensitivity to other drugs.

Hypersensitivity to penicillins
As with other cephalosporins, cefixime should be given with caution to patients with a history of hypersensitivity to penicillin, as there is some evidence 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 Suprax, the drug should be discontinued and the patient treated with appropriate agents if necessary.

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

Acute renal failure

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.

Renal impairment
Cefixime tablet 200 mg should be administered with caution in patients with markedly impaired renal function. 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.

Interaction with other medicinal products and other forms of interaction Anticoagulants
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.
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.

Other forms of interaction
A false positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions 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.

Pregnancy and Lactation

There are no adequate and well-controlled studies in pregnant women. Cefixime Tablet 200 mg should therefore not be used in pregnancy or in nursing mothers unless considered essential by the physician.

Effects on ability to drive and use machines
In the case of side effects such as encephalopathy (which may include convulsion, confusion, impairment of consciousness, movement disorders), the patient should not operate machines or drive a vehicle.

Undesirableeffects

The most commonly reported adverse reactions during treatment aredizziness, headache, flushing, dyspepsia, nasalcongestion, nausea, hot flush, visual disturbance, cyanopsia and vision.

Overdose

There is a risk of encephalopathy in cases of administration of beta-lactam antibiotics, including cefixime,particularly in case of overdose or renal impairment.

Adverse reactions seen at dose levels up to 2 g Suprax in normal subjects did not differ from the profileseen in patients treated at the recommended doses.

Cefixime is not removed from the circulation in significant quantities by dialysis.No specific antidote exists. General supportive measures are recommended.

5. PHARMACOLOGICALPROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: third generation cephalosporin, ATC code: J01DD08

Cefixime is an oral third generation cephalosporin which has marked in vitro bactericidal activity against a wide variety of Gram-positive and Gram-negative organisms.

Pharmacokinetic properties

The absolute oral bioavailability of cefixime is in the range of 22-54%. Absorption is not significantly modified by the presence of food. Cefixime may therefore be given without regard to meals.

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. Typically, the peak serum levels following the recommended adult or paediatric doses are between 1.5 and 3 mcg/mL. Little or no accumulation of cefixime occurs following multiple dosing.

The pharmacokinetics of cefixime in healthy elderly (age > 64 years) and young volunteers (11-35) compared the administration of 400 mg doses once daily for 5 days. Mean Cmax and AUC values were slightly greater in the elderly. Elderly patients may be given the same dose as the general population.

Cefixime is predominantly eliminated as unchanged drug in the urine. Glomerular filtration is considered the predominant mechanism. Metabolites of cefixime have not been isolated from human serum or urine.

Serum protein binding is well characterised for human and animal sera; cefixime is almost exclusively bound to the albumin fraction, the mean free fraction being approximately 30%. Protein binding of cefixime is only concentration dependent in human serum at very high concentrations which are not seen following clinical dosing.

Preclinical safety data

None Stated

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

MCC PH 102
Starch USP
Magnesium Stearate
Sodium Starch glycolate
Talcum
Aerosil
Cross carmellose sodium
Aspartame USP
Ess. Mix Fruit dry powder
Kyron T-314 Speci.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months from the date of manufacture

6.4 Special precautions forstorage

Store below 30ºC. Protect from light.

6.5 Nature and contents of container <and special equipment for use, administration orimplantation>

1 x 10 tablets packed in Alu-Alu blister.

6.6 Special precautions for disposal <and other handling

No special requirement

7. <APPLICANT/MANUFACTURER>

Applicant: TIM GREAT PHARMA VENTURES LTD
No. 39, Niger street, Off M/M Way, Opposite Glo office, Kano, Kano, NIgeria.

Manufacturer: KRUX PHARMA PVT LTD
BALDA Industrial Park, Plot
10/C & 11C
Survey No.256/P-1, Village –
Balda, Taluka: Pardi, District-
Valsad 396125

8. **Marketing authorisation number(s)**

9. Date of first authorisation/renewal of the authorisation

10. Date of revision of the text