MODULE 1 – ADMINISTRATIVE PARTICULARS OF THE PRODUCT

1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1.3.1.1. Name of the medicinal product:

Claxime Tablets

1.3.1.1.1 (Invented) name of the medicinal product:

Generic Name/INN Name: Cefixime and Clavulanate Potassium Tablets

1.3.1.1.2 Strength:

Cefixime USP (as Trihydrate) eq. to

Anhydrous Cefixime 200 mg

Potassium Clavulanate Diluted BP

Eq. to Clavulanic acid 125 mg

1.3.1.1.3 Pharmaceutical form:

Solid Oral Dosage Form- Tablet

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1.3.1.2. Qualitative and Quantitative composition:

Sr. No.	Ingredients	Specification	Label Claim (mg)	Overages (%)	Qty./ Tablet (mg)	% w/w	Function
Mixing							
1	Cefixime (Trihydrate)	USP	200	0.00	200.00	30.67	Active
2	Clavulanate Potassium with Avicel in 1:1 Ratio (MCC)	BP	125	5.00	131.25	20.13	Active
3	Sodium Starch Glycollate	BP	--	0.00	262.662	40.29	Disintegrant
Lubrication							
4	Croscarmellose Sodium	BP	--	0.00	20.00	3.07	Disintegrant
5	Purified Talc	BP	--	0.00	9.245	1.42	Lubricant
6	Colloidal Anhydrous Silica	BP	--	0.00	5.598	0.86	Glidant
7	Magnesium Stearate	BP	--	0.00	11.245	1.72	Lubricant
Total weight of uncoated Tablet					640.00		
Coating							
8	Isopropyl Alcohol	BP	--	0.00	160.00	--	Solvent
9	Methylene Chloride (Dichloromethane)	BP	--	0.00	240.00	--	Solvent
10	Col. Opadry White 21K58794	In-House	--	0.00	12.00	1.84	Coating agent
Total weight of coated Tablet					652.00	100.00	

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1.3.1.3. Pharmaceutical form:

Dosage Form: Solid Oral Dosage Form- Tablet

Visual & Physical characteristics of the product: White coloured, capsule shaped, biconvex, film coated tablet, having one side plain and breakline on other side of tablet.

1.3.1.4. Clinical particulars

1.3.1.4.1. Therapeutic indications:

Cefixime-Clavulanate Potassium should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Cefixime-Clavulanate Potassium is indicated for the treatment of:

Uncomplicated Urinary Tract Infections caused by Escherichia coli and Proteus mirabilis.

Otitis Media caused by Haemophi/us influenzae (beta-lactamase positive and negative strains), Moraxella (Branhamella) catarrha/is, (most of which are beta-lactamase positive) and S. pyogenes.

Pharyngitis and Tonsillitis, caused by S. pyogenes.

Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis, caused by Streptococcus pneumoniae and Haemophilus influenzae (beta- lactamase positive and negative strains).

Uncomplicated gonorrhea (cervical/urethral), caused by Neisseria gonorrhoeae (penicillinase- and non-penicillinase- producing strains).

1.3.1.4.2. Posology and method of administration:

For Tablets:

Adults and Children over 10 Years: One tablet twice daily. The usual course of treatment is 7 days. This may be continued for up to 14 days if required.

1.3.1.4.3. Contraindications:

Cefixime-Clavulanate Potassium is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

1.3.1.4.4. Special warnings and precautions for use:

Persons allergic to penicillin-type antibiotics or other cephalosporin antibiotics should use this medication with caution.

Cefixime should be administered with caution in adult patients with creatinine clearance< 20 ml /min

This medication is removed by the kidneys and kidney function declines in elder age. Therefore, elderly people may be more sensitive to this drug so they should use this medication with caution. Cefixime should be discontinued if diarrhoea is severe.

Prolonged use of Cefixime may result in the over growth of non-susceptible organisms.

1.3.1.4.5. Interaction with other medicinal products and other forms of interaction:

Carbamazepine: Elevated carbamazepine levels have been reported when cefixime is administered concomitantly.

Warfarin and Anticoagulants: Increased prothrombin time, with or without clinical bleeding, has been reported when cefixime is administered

concomitantly.

Oral Contraceptives: Cefixime may interfere with the effectiveness of birth control pills.

Glucose Test: A false positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with copper sulphate testtablets.

Coombs test: A false positive direct Coombs test has been reported during treatment with cephalosporin antibiotics.

1.3.1.4.6. Pregnancy and lactation:

This medication should be used only when clearly needed during pregnancy.

This drug passes into breast milk. While there have been no reports of harm to nursing infants, consult your doctor before breast-feeding.

1.3.1.4.7. Effects on ability to drive and use machines:

Not Know

1.3.1.4.8. Undesirable effects:

The most frequent adverse reactions seen with Cefixime-Clavulanate Potassium are diarrhoea and stool changes. Events like nausea/vomiting, transient elevation in livertransaminases, alkaline phosphatase and jaundice can also occur.

Thrombocytosis, thrombocytopenia, leucopenia, hypereosinophilia, neutropenia and agranulocytosis may also occur.

Other adverse events that may occur are abdominal pain, abdominal cramps, flatulence, indigestion, headache, vaginitis, vulvar itch, rash, hives, itch, dysuria, chills, chest pain, shortness of breath, mouth ulcers, swollen tongue, sleepiness, thirst, anorexia.

Rare but very serious adverse reactions of cefixime includes: yellowing eyes/skin, dark urine, unusual tiredness, new signs of infection (e.g., persistent sore throat, fever), easy

bruising/bleeding, change in the amount of urine, mental/mood changes (such as confusion).This medication may rarely cause a severe intestinal condition (Clostridium difficile-associated diarrhea) due to a resistant bacteria. This condition may occur weeks to months after treatment has stopped. Following side effects may develop: persistent diarrhea, abdominal or stomach pain/cramping, or blood/mucus in your stool.

Use of this medication for prolonged or repeated periods may result in oral thrush or a new vaginal yeast infection (oral or vaginal fungal infection).

Symptoms of a serious allergic reaction may include: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

1.3.1.4.9. Overdose:

There is no experience with overdoses with Cefixime-Clavulanate Potassium.

Adverse reactions seen at dose levels up to 2 g Cefixime in normal subjects did not differ from the profile seen in patients treated at the recommended doses. Gastric lavage may be indicated in over dosage. No specific antidote exists. Cefixime is not removed from the circulation in significant quantities by dialysis.

1.3.1.5. Pharmacological properties:

1.3.1.5.1. Pharmacodynamics properties:

1.3.1.5.2. Pharmacokinetic properties:

Cefixime is a semisynthetic, third generation cephalosporin antibiotic, effective against a wide spectrum of sensitive Gram positive, Gram negative and anaerobic bacterial pathogens including beta-lactamase producing strains. It has high affinity for penicillin binding proteins with varying site of activity. It acts by inhibition of bacterial cell-wall synthesis. The elimination half-life is about 3 hours, with little variation over the usual therapeutic dosage range.

Clavulanic acid is a naturally derived beta lactamase inhibitor produced by Streptomyces clavuligerus. Clavulanic acid is an irreversible inhibitor of intracellular and extracellular lactamases, demonstrating concentration-dependent and competitive inhibition.

Mechanism of action

The combination of cefixime and clavulanic acid (B-lactamase inhibitor) provides a solution for treatment of bacterial infections caused by beta lactam resistant pathogens.

Cefixime is used to treat multiple bacterial infections in different parts of the body.

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Cefixime and clavulanic acid can be used as a second line therapy where cefixime alone is not able to show its bacteriocidal activity.

Clauvanic acid acts as B-lactamase inhibitor, thus making cefixime effective against resistant becteria. Cefixime has been shown to be active against most strians of the following organism both in vitro and in clinical infections. Gram-positive Organisms: Streptococcus pneumoniae, Streptococcus pyogenes Gram-negative microorganisms: Haemophilus influenzae , Moraxella (Branhamella) catarrhalis (most of which are beta-lactamase positive), Escherichia coli,Proteus mirabilis,Neisseria gonorrhoeae (including penicillinase and nonpencillinase producing strains). Cefixime has been shown to be active in vitro against most strains of the following organism; however, clinical efficacy has not been established.

Gram Positive Organism: Streptococcus agalactiae

Gram-negative Organism: Haemophilus parainfluenzae (beta-lactamse positive and negative strains),Proteus vulgaris, Klebsiella pneumoniae, Klebsiella oxytoca, Pasteurella multocida, Providencia species,Salmonella species, Shigella species, Citrobacter amalonaticus, Citrobacter diversus, Serratia marcescens.

1.3.1.6. Pharmaceutical particulars:

1.3.1.6.1. List of Excipients:

Sr.no	Excipients name
1.	Sodium Starch Glycollate
2.	Croscarmellose Sodium
3	Purified Talc
4	Colloidal Anhydrous Silica
5	Magnesium Stearate
6	Isopropyl Alcohol
7	Methylene Chloride (Dichloromethane)
8	Col. Opadry White 21K58794

1.3.1.6.2. Incompatibilities:

Not Available

1.3.1.6.3. Shelf life:

24 months

1.3.1.6.4. Special precautions for storage:

Store below 30°C. Protect from light & moisture.

1.3.1.6.5. Nature and contents of container:

1×10 Tablets in Alu-Alu blister pack. Such one blister packed in one monocarton along with pack insert.