1. NAME OF THE MEDICINAL PRODUCT

TALSURE 500 Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:

Cefuroxime Axetil USP

Eq. to Anhydrous Cefuroxime ……500 mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet

A White to off white, Oval shaped, Biconvex, Film coated tablets, plain on both sides.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

- Acute streptococcal tonsillitis and pharyngitis.
- Acute bacterial sinusitis.
- Acute otitis media.
- Acute exacerbations of chronic bronchitis.
- Cystitis.

4.2. Posology and method of administration

4.2.1.Posology

The usual course of therapy is seven days

Adults and children (≥40 kg)

Acute tonsillitis and pharyngitis, acute bacterial sinusitis	250 mg twice daily
Acute otitis media	500 mg twice daily
Acute exacerbations of chronic bronchitis	500 mg twice daily
Cystitis	250 mg twice daily

4.2.2.Method of administration

Oral Administration Only

4.3. Contraindications

- Patients with known hypersensitivity to cephalosporin antibiotics.
- Severe hypersensitivity (e.g. anaphylactic reaction) to any other type of Beta lactam antibacterial agent (Penicillins, Monobactams and Carbapenems).

4.4. Special warnings and precautions for use

Special care is indicated in patients who have experienced an allergic reaction to Penicillins or other Beta-lactam antibiotics because there is a risk of cross-sensitivity. As with other antibiotics, use of Cefuroxime Axetil may result in the overgrowth of Candida.

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

Drugs which reduce gastric acidity may result in a lower bioavailability of Cefuroxime Axetil compared with that of the fasting state and tend to cancel the effect of enhanced absorption after food.

4.6. Pregnancy and Lactation

Pregnancy: TALSURE 500 tablets should be prescribed to pregnant women only if the benefit outweighs the risk.

Breast-feeding: Cefuroxime should only be used during breastfeeding after benefit/risk assessment by the physician in charge.

Fertility: There are no data on the effects of cefuroxime Axetil on fertility in humans.

4.7. Effects on ability to drive and use machines

None Know

4.8. Undesirable effects

Common: Headache, Dizziness, Candida Overgrowth

Uncommon: Skin rash, Vomiting

4.9. Overdose

- Overdose can lead to neurological sequelae including encephalopathy, convulsions and coma. Symptoms of overdose can occur if the dose is not reduced appropriately in patients with renal impairment.
- Serum levels of cefuroxime can be reduced by hemodialysis and peritoneal dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamics properties

Pharmacotherapeutic group: antibacterial for systemic use, second-generation Cephalosporin

ATC code: J0ICR02.

Cefuroxime Axetil undergoes hydrolysis by esterase enzymes to the active antibiotic, cefuroxime. Cefuroxime inhibits bacterial cell wall synthesis following attachment to penicillin binding proteins (PBPs). This results in the interruption of cell wall (peptidoglycan) biosynthesis, which leads to bacterial cell lysis and death.

5.2. Pharmacokinetic properties

Absorption: After oral administration Cefuroxime Axetil is absorbed from the gastrointestinal tract and rapidly hydrolyzed in the intestinal mucosa and blood to release cefuroxime into the circulation.

Distribution: Cefuroxime passes the blood-brain barrier when the meninges are inflamed.

Biotransformation: Cefuroxime is not metabolized.

Elimination: Cefuroxime is excreted by glomerular filtration and tubular secretion.

5.3. Preclinical safety data

Convential studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

- Microcrystalline Cellulose PH 102
- Croscarmellose Sodium
- Cross Povidone
- Colloidal Anhydrous Silica
- Sodium Citrate
- Sodium Bicarbonate
- Purified Talcum
- Kyron T 314
- Magnesium Stearate
- Hydroxy Propyl Methyl Cellulose (E-5)
- Hydroxy Propyl Methyl Cellulose (E-15)
- Diethyl Phthalate
- Titanium Dioxide

6.2. Incompatibilities

No known significant incompatibilities

6.3. Shelf life

24 Months

6.4. Special precautions for storage

Store in a cool, dry place below 25°C. Protect from light.

Keep medicine out of reach of children.

6.5. Nature and contents of container

10 Tablets in one ALU-ALU blister, and 01 such blister packed in a one carton with insert.

6.6. Special precautions for disposal and other handling.

No special instructions for use or handling.

7. Marketing authorization Holder

Manufactured by

BRUSSELS LABORATORIES PVT. LTD.

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