	MODULE 1 APPLICATION INFORMATION
PRODUCT NAME:	CEDOCLAV 625 (Cefuroxime and Clavulanate Potassium Tablets 625 mg)

1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. *NAME OF THE MEDICINAL PRODUCT*

CEDOCLAV 625 (Cefuroxime and Clavulanate Potassium Tablets 625 mg)

2. *QUALITATIVE AND QUANTITATIVE COMPOSITION*

Composition:
Each film coated tablet contains:
Cefuroxime Axetil USP
equivalent to Cefuroxime..... 500 mg
Clavulanate Potassium USP
Equivalent to Clavulanic Acid ..... 125 mg
Excipients q.s

For full list of excipients, see section 6.1.

3. *PHARMACEUTICAL FORM*

Film Coated Tablet
Off white elongated biconvex film coated tablet.

4. *Clinical particulars*

4.1 Therapeutic indications

CEDOCLAV 625 Tablet is a combination medicine that is used to treat various types of bacterial infections. It fights against the microorganisms to prevent their growth and further spread of the infection.

4.2 Posology and method of administration

As directed by the physician. OR

For age group 13 - 18 years (Adolescent):
Disease: Sinusitis
Single Maximum Dose: 250 mg
Frequency: 2 daily
Course Duration: 10 days

For Adults:
Disease: Sinusitis
Single Maximum Dose: 250 mg
Frequency: 2 daily
Course Duration: 10 days

For Geriatric
Disease: Sinusitis
Single Maximum Dose: 250 mg
Frequency: 2 daily
Course Duration: 10 days

Method of Administration:

CEDOCLAV Tablet may be taken with or without food, but it is better to take it at a fixed time.

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4.3 Contraindications

CEDOCLAV Tablet should not be used by the patient if he has a known history of allergy to medicines belonging to this medication or any other medication belonging to fluoroquinolones.

Do not take this medication if you have a past history of tendinitis or tendon rupture after using CEDOCLAV Tablet.

Avoid taking this medication if you have a past or family history of suffering from Myasthenia Gravis (weakness and rapid fatigue of muscles under voluntary control).

4.4 Special warnings and precautions for use

- Diarrhoea

CEDOCLAV 625 Tablet can cause diarrhoea because it may also kill the helpful bacteria in your stomach or intestine. Inform your doctor if you experience severe diarrhoea while receiving this medicine.

- Liver disease

Regular monitoring of the liver enzyme levels is recommended while taking CEDOCLAV 625 Tablet and even after completion of the treatment with this medicine.

- Antibiotic resistance

Antibiotic resistance occurs when bacteria develop the ability to defeat the medicine that was intended to kill them. Hence, to avoid such resistance you should always complete the entire course of treatment with CEDOCLAV 625 Tablet even if you feel better after taking few doses.

- Use in children

CEDOCLAV 625 Tablet is not recommended for use in children below 12 years of age because the safety and efficacy data is not available.

- Jarisch-Herxheimer reaction

CEDOCLAV 625 Tablet may cause Jarisch-Herxheimer reaction in some patients when used for more than 7 days. The symptoms may include fever, chills, headache, low blood pressure, increased heart rate, etc.

4.5 Interaction with other medicinal products and other forms of interaction

Drug-Drug Interactions: CEFUROXIME+CLAVULANATE POTASSIUM may have interaction with antacid (esomeprazole, omeprazole), anticoagulants (warfarin), anti-gout (probenecid), diuretics (furosemide), oral contraceptives (estrogen, progesterone).

Drug-Food Interactions: No interactions found/established.

Drug-Disease Interaction: Inform your doctor if you have colitis (inflammation in the lining of the colon), seizures, dialysis, kidney and liver dysfunction.

4.6 Fertility, Pregnancy and Lactation

Pregnancy

CEDOCLAV Tablet is safe to use in pregnancy to treat bacterial infections. However, it is recommended to use this medicine only after consulting your doctor.

Lactation

CEDOCLAV Tablet is safe to use during breastfeeding. It enters into breast milk at low levels. However, your doctor prescribes this medicine only if the benefits outweigh the risks. If it is used in your breastfeeding, the baby should be observed for symptoms such as diarrhoea and yeast infection.

4.7 Effects on ability to drive and use machines

It usually does not impair your ability to drive, but you should not drive if it makes you feel sleepy or dizzy.

4.8 Undesirable effects

Common side effects are:

Nausea

Vomiting

Diarrhea

Increased liver enzymes

Allergic reaction

4.9 Overdose

Do not consume more than the recommended dose, as this may have harmful effects on your body.
Doctor consultation is recommended if an overdose is suspected. Immediate medical attention may be needed in such situation.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Cefuroxime works by preventing the formation of bacterial cell covering, which is necessary for their survival. Thereby, kills the bacteria. Clavulanic acid works by decreasing bacterial resistance and enhancing the activity of cefuroxime against the bacteria. Together, CEFUROXIME+CLAVULANIC ACID helps to treat bacterial infections.

5.2 Pharmacokinetic properties

CEFUROXIME AXETIL :
Absorption: It is absorbed from the gastrointestinal tract and rapidly hydrolyzed by nonspecific esterases in the intestinal mucosa.
Distribution: It is distributed throughout the extracellular fluids. Approximately 50% of serum cefuroxime is bound to protein.
Metabolism: The axetil moiety is metabolized to acetaldehyde and acetic acid.
Elimination: Excretion occurs mainly through the kidney both by glomerular filtration and tubular secretion.

CLAVULANATE POTASSIUM:
Absorption: Well absorbed aprx. 75%.
Distribution: Clavulanate cross the placental barrier, and low concentrations appear in breast milk. Clavulanate Potassium have minimal protein-binding of 22% to 30% to human serum.
Metabolism: It is metabolized in the Hepatic. The metabolic fate of clavulanate potassium is not completely identified, but it appears to undergo extensive metabolism.
Excretion: It is excreted by glomerular filtration.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to the data already provided in other sections of this Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cross Carmellose Sodium, Magnesium Stearate, Aerosil, Talcum, Micro Crystalline Cellulose, Cross Povidone, Colorozy, Isopropyl Alcohol, Methylene Dichloride.

6.2 Incompatibilities

None known

6.3 Shelf life

Product as packaged for sale: 24 months.

6.4 Special precautions for storage

Store below 30 °C. Protect from light & moisture.
Keep out of reach of children.

6.5 Nature and contents of container

Alu-Alu blister of 1 x 10's Tablets with transparent plastic pouch and Silica gel in a mono carton along with a pack insert.

6.6 Special precautions for disposal

Not applicable

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7. *Applicant/Holder of Certificate of Product Registration*

LAVINA PHARMACEUTICALS PVT. LTD.
Office No. 402, 4th floor, Satra Plaza,
Plot no. 19/20, sector – 19D, Vashi,
Navi Mumbai – 400703, INDIA.
Telephone:+ 91-22-2783 1450/27830 1452 /27830 1454 / 2783 1455.
E-mail: regulatory@lavinapharma.com

8. *Drug Product Manufacturer*

MAXMED LIFESCIENCES PVT LTD.
Plot No-54 & 55, Sector-IIDC, SIDCUL,
Rudrapur, Udhamsingh Nagar, Uttarakhand.
India.

9. *NAFDAC Registration number(s)*

Not assigned


95.00 mm
10.00 mm
CEDOCLAV 625
Cefuroxime and Clavulanate
Potassium Tablets 625 mg
1x10 Tablets
STILL
CEDOCLAV 625
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Cefuroxime and Clavulanate
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Clavulanate Potassium USP
Equivalent to Clavulanic Acid.....125 mg
Excipients .....q.s.
Dosage: As directed by the Physician.
Storage: Store below 30°C.
Protect from light & moisture.
Keep out of reach of children.
Prescription Only Medicine.
Mfg. Lic. No.: 150/UA/SC/P-2007
Batch No.:
Mfg. Date:
Exp. Date:
NAFDAC Reg.No.:
OPZ
(20 x 18mm)
Imported by:
DE-STILL PHARMACY LTD
No.15, Kulantan Street off Sheriff Hotel,
Odogunyan Ikorodu Lagos state, Nigeria.
Exported by :
LAVINA PHARMACEUTICALS PVT. LTD
Office No.402, 4th Floor, Satra Plaza, Plot No.19 20,
Sector 19 D, Vashi, Navi Mumbai 400 703, INDIA.
Manufactured in India by:
M/s MAXMED LIFESCIENCES PVT. LTD.
Plot No 54 & 55, Sector IIDC , SIDCUL,
Rudrapur, Udhamsingh Nagar,
Uttarakhand, INDIA.
CEDOCLAV 625
CEDOCLAV 625


153.00 mm
8.50 mm
136.00 mm
8.50 mm
58.00 mm
CEDOCLAV 625
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