SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product
IMICIL-500

Pharmaceutical form

Dry Powder for Injection

2. Qualitative and quantitative composition

Each vial contains:
Imipenem USP
Equivalent to anhydrous Imipenem…500mg
Cilastatin Sodium USP
Equivalent to Cilastatin …….500mg
Sodium bicarbonate added as a buffer

3. Pharmaceutical form

Dry powder for Injection

A white to almost white or pale yellow powder filled in 30 ml clear glass vial, sealed with grey bromo butyl rubber stopper and dark green coloured flip off seal.

4. Clinical particulars

4.1 Therapeutic indications

Imipenem Cilastatin is indicated for the treatment of the following infections in adults and children 1 year of age and above:

- Complicated intra - abdominal infections
- Severe pneumonia including hospital and ventilator associated pneumonia
- Intra & post- partum infections
- Complicated urinary tract infections
- Complicated skin and soft tissue infections
- Imipenem Cilastatin may be used in the management of the neutropenic patients with fever that is suspected to be due to bacterial infections.
- Treatment of patients with bacteremia that occurs in association with any of the infection listed above. Consideration should be given to official guidance on the appropriate use of the antibacterial agents.

4.2 Posology and method of administration

Posology:

The total daily dosage of Imipenem/Cilastatin should be based on the type or severity of infection, the pathogen(s) isolated, renal function and bodyweight.

Adults and adolescents

For patients with normal renal function (creatinine clearance of 70 ml/min/1.73 m^2), the recommended dose regimen is:
500 mg/500mg every 6 hours OR
1000mg/1000mg every 8 hours or every 6 hours

It is recommended that infections suspected or proven to be due to less susceptible bacteria species (such as Pseudomonas aeruginosa) and very severe infections (in neutropenic patients with fever) should be treated with 1000 mg/1000 mg administered every 6 hours.

A reduction in dose is necessary when:

- Creatinine clearance is 70 ml/min/1.73 m^2 or
- Body weight is ≤70 kg, the proportionate dose for patients ≤70kg would be calculated using the following formula:

$$\frac{\text{Actual body weight (kg)} \times \text{Standard dose}}{70 \text{ kg}}$$

The maximum total daily dose should not exceed 4000mg/4000mg per day

Renal Impairment

To determine the reduced dose or adults with impaired renal function:

1. The total daily dose that would be applicable to patients with normal renal function should be selected
2. From table 1 the appropriate reduced dose regimen is selected according to the patient's creatinine clearance.

Table for reduced dose in adults with renal impairment and body weight ≥70 kg

Total daily dose for patients with normal renal functions (mg/day)	Creatinine clearance (ml/min/1.73 m^2)		
	41-70	21-40	6-20
	Dose in mg (interval hrs.)		
2000/2000	500/500 (8)	250/250(6)	250/250 (12)
3000/3000	500/500(6)	500/500 (8)	500/500(12)
4000/4000	750/750(8)	500/500 (6)	500/5009(12)

Patients with a creatinine clearance of 5 ml/min/1.73m^2

These patients should not receive Imipenem/ Cilastatin unless hemodialysis is instituted within 48 hours

Patients on Hemodialysis

When treating patients with creatinine clearance of 5 ml/min/1.73m2 who are undergoing dialysis use the dose recommendation for patients with creatinine clearance of 6 to 20 ml/min/1.73m^2
Both Imipenem and Cilastatin are cleared from the circulation during hemodialysis. The patients should receive Imipenem/Cilastatin after hemodialysis and at 12 hours' interval timed from the end of hemodialysis sessions. dialysis patients, especially those with background central nervous system disease, should be carefully mentioned, for patients on hemodialysis Imipenem Cilastatin is recommended only when the benefit out weight the potential risk of seizures.
Currently there are inadequate data to recommend the use of Imipenem/ Cilastatin for patients on dialysis

Hepatic impairment

No dose adjustment is required for patients with hepatic impairment

Elderly populations
No dose adjustment is required for the elderly patients with normal renal function

Pediatric Populations:
For pediatric patients ≥1year of age, the recommended dose is 15/15 or 25/25 mg/kg dose administered every 6 hour
It is recommended that infections suspected or proven to be less susceptible bacterial species (such as Pseudomonas aeruginosa) and very severe infections (in neutropenic patients with fever) should be treated with 25/25mg/kg administered every 6 hours

Pediatric population < 1 year of age:
The clinical data is insufficient to recommend dosing for children <1 year of age

Pediatric population with renal impairment
The clinical data is insufficient to recommend dosing for pediatric patients with renal impairment

Method of administration
Imipenem/Cilastatin is to be reconstituted and further diluted prior to administration.
Each dose of ≤500/500mg should be given Intravenous infusion over 20 to 30 minutes.
Each dose of >500/500 mg should be infused over 40 to 60 minutes. In patients, who develop nausea, rate of administration should be further slowed.

4.3 Contraindications

Contraindicated for the patients with known hypersensitivity to Imipenem and Cilastatin

4.4 Special warnings and precautions for use

General
The selection of Imipenem /Cilastatin to treat and individual patient should take into account the appropriateness of using a carbapenem antibacterial agents based on factors such as severity of infections, the prevalence of resistance to other suitable antibacterial agents and the risk of selecting for carbapenem – resistant bacteria.

Hypersensitivity
Serious and occasionally fatal hypersensitivity reactions have been reported in patients receiving therapy with beta- lactams. These reactions are more likely to occur in individuals with a history of sensitivity to multiple allergens. Before initiating therapy with Imipenem/Cilastatin, careful inquiry should be made concerning previous hyper sensitivity reaction to carbapenem, penicillin, cephalosporin, other beta lactam, and other allergens. If an allergic reaction to Imipenem/Cilastatin occurs, discontinue the therapy immediately. **Serious anaphylactic reaction requires immediate emergency treatment.**

Hepatic
Hepatic functions should be closely monitored during treatment with Imipenem/Cilastatin due to the risk of hepatic toxicity

Use in patients with liver disease: patients with pre-existing liver disorder should have liver function monitored during the treatment with Imipenem/ Cilastatin. There is no dose adjustment necessary.

Hematology

A positive direct or indirect comb test may have developed during treatment with Imipenem/Cilastatin

Antibacterial Spectrum

The antibacterial spectrum of Imipenem Cilastatin should be taken into account especially in life threatening conditions before embarking on any empiric treatment. Furthermore, due to the limited susceptibility of specific pathogen associated with Imipenem Cilastatin, caution should be exercised. The use of Imipenem/Cilastatin is not suitable for treatment of these types of infections unless the pathogen is already documented and known to be susceptible or there is very high suspicion that the most likely pathogens would be suitable for treatment. Concomitant use of an appropriate anti-MRSA agent may be indicated when MRSA infection is suspected or proven to be involved in the approved indications.

Concomitant use of an aminoglycoside may be indicated when Pseudomonas aeruginosa infections are suspected or proven to be involved in the approved indications.

Infections with valproic acid

The concomitant use of Imipenem/ Cilastatin and valproic acid /sodium valproate is not recommended

Clostridium difficile

Antibiotic associated colitis and pseudomembranous colitis have been reported with Imipenem Cilastatin ad with nearly all other anti-bacterial agents and may range from mild to the life threatening in severity. It is important to consider this diagnosis in patients who develop diarrhea during or after the use of Imipenem Cilastatin. Discontinuation of therapy with Imipenem Cilastatin and the administration of specific treatment for clostridium difficile should be considered. Medicinal products that inhibit peristalsis should not be given.

Meningitis

Imipenem Cilastatin is not recommended for the therapy of meningitis

Renal Impairment

Imipenem Cilastatin accumulates in patients with reduced kidney functions. CNS adverse reactions may occur if the dose is not adjusted.

Central Nervous System

CNS adverse reactions such as myoclonic activity, confusional states, or seizures have been reported especially when recommended doses based on renal function and body weight were exceeded. These experiences have been reported most commonly in patients with CNS disorders and/or compromised renal function in whom accumulation of the administered entities could occurs. Hence, close adherence to recommended dose schedules is urged especially in these patients. Anticonvulsants therapy should be continued in patients with a known seizure disorder.

Special awareness should be made to neurological symptoms or convulsion in children with known risk factors for seizures or on concomitant treatment with medicinal products lowering the seizures threshold.

If focal tremors, myoclonus or seizures occurs, patients should be evaluated neurologically and placed on anticonvulsant therapy if not already instituted. If CNS symptoms continue, the dose of Imipenem/Cilastatin should be decreased or discontinued.

Patients with creatinine clearances of 5 ml/min/1.73m^2 should not receive Imipenem/Cilastatin unless hemodialysis is instituted within 48 hours. For patients on hemodialysis, Imipenem/ Cilastatin is recommended only when the benefits outweigh the potential risk of seizures.

Pediatric population

Clinical data are insufficient to recommend the use of Imipenem/Cilastatin in children under 1 year of age or pediatric patients with impaired renal function.

Imipenem/Cilastatin 500 mg/500mg contains 37.5 mg of sodium which should be taken into consideration by patients on

a controlled sodium diet.

4.5 Interaction with other medicinal products and other forms of interaction

General seizures have been reported in patients who received ganciclovir and Imipenem/Cilastatin. These drugs should not be used concomitantly unless the potential benefit outweighs the risk.

Decrease in valproic acid level that may fall below the therapeutic range have been reported when valproic acid was co administered with carbapenem agent. The lowered valproic acid levels can lead to inadequate seizure control, therefore, concomitant use of Imipenem and valproic acid/sodium valproate is not recommended and alternative antibacterial or anti convulsant therapies should be considered.

Oral anti-coagulant

Simultaneous administration of antibiotics with warfarin may augment its anti-coagulant effects. There have been many reports of increases in the anti-coagulant effects of orally administered anti-coagulant agents. including warfarin in patients who are concomitantly receiving antibacterial agents. The risk may vary with the underlying infections, age and general status of the patient so that the contribution of the antibiotic to the increase in INR is difficult to access. It is recommended that the INR should be monitored frequently during and shortly after co-administered of antibiotics with an oral anti-coagulant agent.

Concot administration of Imipenem/Cilastatin and probenecid resulted in minimal increases in the plasma levels and plasma half – life of Imipenem. The urinary recovery of active (non -metabolized) Imipenem decreased to approximately 60% of the dose when Imipenem/Cilastatin and probenecid doubled the plasma level and half-life of Cilastatin, but had no effect on urine recovery of Cilastatin.

4.6 Fertility, pregnancy and lactation

Pregnancy

Pregnant monkey showed evidence of maternal and foetal toxicity with bolus injections at does twice to the human dose

There are no adequate data for the use of Imipenem/Cilastatin in pregnant women. The potential risk for humans is unknown. Therefore, Imipenem/Cilastatin should not be given in pregnancy unless the anticipated benefit to the mother outweighs the possible risk to the fetus.

Imipenem and Cilastatin has been detected in human milk. If the use of Imipenem and Cilastatin is deemed essential, the mother should stop breast-feeding.

4.7 Effects on ability to drive and use machines

There is no specific data however some of CNS side effects such a dizziness, psychic disturbance, confusion and seizures, may affect the ability to drive and operate machinery

4.8 Undesirable effects

Frequencies in this table are defined using the following convention: very common (>1/10) common (>1/100), uncommon (>1/1000,<1/100), rare (>1/10000,<1/1000), very rare (<1/10000), not known (cannot be estimated from the available data).

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness

System Organ Class	Frequency	Event

Infections and infestations	Rare	Pseumembranous colitis, candiasis
	Very Rare	Gastro-enteritis
Blood and lymphatic system disorders	Common	eosinophilia, thrombocytosis,
	Uncommon	leukopenia, decreased haemoglobin and prolonged prothrombin time.
	Rare	neutropenia including agranulocytosis, pancytopenia, haemolytic anaemia
	Very Rare	depression of the bone marrow

Immune system disorders	Rare	anaphylactic reactions
Nervous system disorders	Uncommon	myoclonic activity, dizziness
	Rare	Paraesthesia, focal tremor
	Very Rare	Aggravation of myasthenia gravis, headache
Ear and labyrinth disorders	Rare	hearing loss
	Very Rare	Vertigo, tinnitus
Cardiac disorders	Very Rare	hypotension
Vascular Disorder Respiratory, thoracic and mediastinal disorder	Common	Thrombophlebitis
	Uncommon	Hypotension
	Very rare	Flushing
	Very rare	Dyspnoea, hyperventilation, pharyngeal pain
Gastrointestinal disorders	common	nausea, vomiting, diarrhoea,
	Rare	Staining of teeth and/ or tongue
	Very Rare	Haemorrhagic colitis, abdominal pain, heartburn, glossitis.
Hepatobiliary disorders	Rare	hepatitis with liver failure.
	Very rare	fulminate hepatitis
Skin and subcutaneous tissue disorders	Common	rash
	uncommon	Urticarial, pruritus
	Rare	toxic epidermal necrolysis, exfoliative dermatitis
	Very rare	hyperhidrosis, skin texture changes
Musculoskeletal and connective tissue disorders	Very rare	Polyarthralgia, thoracic spine pain
Renal and urinary disorders	Rare	acute renal failure, polyuria, urine discoloration.

Reproductive system and breast disorder	Very Rare	Pruritus vulvae
General disorders and administration site conditions	Uncommon	Fever, local pain and induration at the injection site, erythema at the injection site
	Very common	Chest discomfort, asthenia/ weakness
Investigations	Common	Increase in serum transaminases, increase in serum alkaline phosphatase
	uncommon	A positive direct coombs test, prolonged prothrombin time, decreased haemoglobin, increase in

Reporting of suspected adverse reaction: Healthcare professional are requested to report any suspected adverse reaction to the National Regulatory Agents.

4.9 Overdose

No specific information is available on the treatment of overdose with Imipenem and Cilastatin
Imipenem-Cilastatin Sodium haemodialysable however usefulness of the procedure in overdose setting is unknown

5 Pharmacological properties
5.1 Pharmacodynamic properties

Pharmacotherapeutic group:
Antibacterial for systemic use. Carbapenem
ATC code: J01D H51

Mechanism of Action

Imipenem/Cilastatin consists of two components: Imipenem and Cilastatin in a ratio 1: 1 ratio by weight.
Imipenem, also referred to as a N-formimidoyl – thienamycin, is a semi-synthetic derivative of thienamycin, the parent compound produced by the filamentous bacterium Streptomyces cattleya.
Imipenem exerts its bactericidal activity by inhibiting bacterial cell wall synthesis in Gram – Positive and Gram-negative bacteria through binding to penicillin – binding proteins (PBP)
Cilastatin sodium is a competitive, reversible and specific inhibitor of dehydropeptidase – I, the renal enzyme which metabolize and inactivates Imipenem. It is devoid of intrinsic antibacterial activity and does not affect the antibacterial activity of Imipenem.
Pharmacokinetics/ Pharmacodynamics (PK/PD) relationship:
Similar to other beta-lactam antibacterial agents, the time that Imipenem Concentration exceed the MIC (T>MIC) has been shown to best correlate with efficacy.

Mechanism of Resistance:
Resistance to Imipenem may be due to:

- Decreased permeability of the outer membrane of Gram – negative bacteria
- Imipenem may be actively removed from the cell with an efflux pump
- Imipenem is stable to hydrolysis by most beta-lactamases, including penicillinase and cephalosporinases produced by gram-positive and gram- negative bacteria, with the exception of relatively rare carbapenem hydrolyzing beta – lactamases. Species resistant to other carbapenem do generally express co –resistance to Imipenem. There is no target based cross resistance between Imipenem and agents of the quinolone, aminoglycoside, macrolide and tetracycline classes.

Breakpoints

EUCAST MIC Breakpoints for Imipenem to separate susceptible (S) pathogens from resistant ® pathogens are as follow:
Susceptibility of staphylococci to carbapenem is inferred from the methicillin susceptibility.
The antibacterial spectrum of Imipenem is as shown below.

Commonly susceptible species
Aerobic Gram-positive
Enterococcus faecalis
Staphylococcus aureus (Methicillin-susceptible)
Staphylococcus coagulase negative (Methicillin-susceptible)
Streptococcus agalactiae

Streptococcus pneumoniae Streptococcus pyogenes "Viridans group" streptococci Aerobic Gram-negative
Acinetobacter baumannii
Citrobacter freundii
Enterobacter aerogenes
Enterobacter cloacae
Escherichia coli
Haemophilus influenzae
Klebsiella oxytoca
Klebsiella pneumonia
Moraxella catarrhalis
Serratia marcescens
Anaerobic
Bacteroides fragilis
Fusobacterium spp. Peptococcus spp.
Peptostreptococcus spp.
Prevotella spp.
Veillonella spp.
Clostridium Spp. (except Clostridium difficile)

Species for which acquired resistance may be a problem

Aerobic Gram-positive
Enterococcus faecium+
Aerobic Gram-negative
Pseudomonas aeruginosa

Inherently resistant organisms

Aerobic Gram-positive
Staphylococcus (Methicillin-resistant)
Aerobic Gram-negative
Stenotrophomonas maltophilia
Anaerobic Gram-positive
Clostridium difficile

Others

Chlamydia spp.
Chlamydophila spp.
Mycoplasma spp.
Legionella pneumophila
Ureaplasma urealyticum

+ Species for which high rates of resistance (> 50%) have been observed in some European countries.

5.2 Pharmacokinetic properties

Plasma Concentration:

In, Intravenous infusion of Imipenem/Cilastatin over 20 minutes resulted in peak plasma

levels of Imipenem ranging from 12 to 20 µg/ml for the 250mg/250mg dose, from 21 to 58 µg/ml for the 500 mg/ 500 mg dose and from 41 to 83 µg/ml for the 1000mg/1000mg dose. The mean peak plasma levels of Imipenem following the 250mg/250mg, 500mg/500mg and 1000mg/1000mg doses were 17, 39 and 66 µg/ml, respectively. At these doses, plasma levels of Imipenem declines to below 1µg/ml or less in four to six hours.
Peak plasma level of Cilastatin, following a 20-minute intravenous infusion of Imipenem/Cilastatin, ranged from 21 to 26 g/ml for the 250 mg/250 mg dose, from 21 to 55 g/ml for 500 mg / 500 mg dose and from 56 to 88 g/ml for the 1000mg/1000mg dose. The mean peak plasma levels of Cilastatin following the 250mg/250mg, 500mg/500mg and 1000mg/1000mg doses were 22, 42 & 72 µg/ml, respectively.
Distribution:

Imipenem is bound to plasma proteins for about 20% and Cilastatin for about 40%.

Biotransformation and Elimination:

When administered alone, Imipenem is metabolized in the kidneys by dehydropeptidase – I. Cilastatin is a specific inhibitor of dehydropeptidase – I enzyme and effectively inhibits metabolism of Imipenem so that concomitant administration of Imipenem and Cilastatin allows therapeutic antibacterial levels to be attained in both urine and plasma.
The plasma half –life of Imipenem was one hour. Approximately 70% of the administered antibiotics was recovered intact in the urine within ten hours and no further urinary excretion was detectable. Urinary concentration of Imipenem exceeded 10 g/ml for up to eight hours after a 500 mg/500mg dose administration. The remainder of the dose was recovered in the urine as antibacterially inactive metabolites and fecal elimination of Imipenem was essentially nil.
No accumulation of Imipenem in plasma or urine has been observed with regimens of Imipenem/Cilastatin administered as frequently as every six hours, in patients with normal renal functions.

The plasma half-life of Cilastatin is approximately one hour. Approximately 70 – 80% of the dose of Cilastatin was recovered unchanged in the urine as Cilastatin within 10 hours of administration of Imipenem/Cilastatin. no further Cilastatin appeared in the urine thereafter. Approximately 10 % was found as the N – acetyl metabolite, which has inhibitory activity against dehydropeptidase comparable to that of Cilastatin. Activity of dehydropeptidase – I in the kidney returned to normal levels shortly after the elimination of Cilastatin from the blood stream.

Elderly:

In healthy elderly volunteers (65 to 75 years of age with normal renal function for their age), the pharmacokinetics of a single dose of Imipenem 500 mg and Cilastatin 500 mg administered intravenously over 20 minutes are consistent with those expected in subjects with slight renal impairment for which no dosage alteration is considered necessary. The mean plasma half-life for Imipenem and Cilastatin were 91± 7 min and 69 ±15 min, respectively. Multiple dosing has no effects on pharmacokinetic of either Imipenem or Cilastatin and no accumulation was observed for either Imipenem or Cilastatin.

Patients with renal impairment:

Following a singe 250 mg/250 mg intravenous dose of Imipenem/Cilastatin, the area under the curve (AUC's) for Imipenem increased 1.1 – fold, 1.9 fold and 2.7 fold in subjects with mild, moderate and severe renal impairment, respectively compared to subjects with normal renal function. And AUC's for Cilastatin increased 1.6 fold, 2.0 fold and 6.2 fold in subject with mild, moderate and severe renal impairment, respectively compared to subjects with normal renal function.
Following a single 25. Mg/250 mg dose of Imipenem/Cilastatin given 24 hours after hemodialysis, AUC's of ipenem and Cilastatin were 3.7 fold and 16.4 fold higher, respectively as compared with normal renal function.

Urinary recovery, renal clearance and plasma clearance of Imipenem and Cilastatin decrease with renal function following Intravenous administration of Imipenem/Cilastatin. Dose adjustment is necessary for patients with impaired renal function.

Hepatic Insufficiency

The pharmacokinetics of Imipenem in patients with hepatic insufficiency have not been established. Due to the limited extent of hepatic metabolism of Imipenem, its pharmacokinetics are not expected to be affected by hepatic insufficiency. Therefore, no dose adjustment is recommended in patients with hepatic impairment.

Pediatric patients

The average clearance and volume of distribution for Imipenem were approximately 45% higher in pediatric patients (3months to 14 years) in compared to adults. The AUC for Imipenem following administration of 15/15 mg/per kg body weight of Imipenem/Cilastatin to pediatric patients was approximately 30% higher than the exposure in adults receiving a 500 mg/500 mg dose. At the higher dose, the exposure following administration of 25/25mg/kg of body weight was 9% higher as compared to the exposure in the adults receiving 1000mg /1000mg.

a. Pharmacokinetic / pharmacodynamics relationship

The action on histamine-induced skin reactions is out of phase with the plasma concentrations

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

Effects in non-clinical studies were observed only at exposures considered sufficiently more than the maximum human exposure indicating little relevance to clinical use.

6 Pharmaceutical particulars

6.1 List of excipients

Sodium (as bicarbonate)

6.2 Incompatibilities

Imipenem/Cilastatin is chemically incompatible with lactate and should not be reconstituted with solvent containing lactate. Imipenem/Cilastatin can, however, be administered into an IV tubing through which a lactate solution is being infused. Imipenem/Cilastatin should not be mixed or physically added to other antibiotics.

This medicinal product must not be mixed with other medicinal products except those mentioned in section on reconstitution and handling.

6.1 Shelf life

24 Months

6.2 Special precautions for storage

Store dry material at 16 to 25^{0}C(68 to 77^{0}F).
After reconstitution Imipenem and Cilastatin can be kept at room temperature (25^{0}C) for upto 4 hours under refrigeration (5^{0}C) for up to 24hours Solution of Imipenem and Cilastatin should not be frozen

6.3 Nature and contents of the container

Imipenem/Cilastatin 500mg/500mg Powder for Solution is available in a Type I clear Tubular glass vial with a bromo butyl rubber plug and polypropylene flip-off seal.
The vial size is 30 ml.
Pack size: 1x1

6.4 Special precautions for disposal

Preparation of intravenous solution

The following table is provided for convenience in reconstituting Imipenem/Cilastatin for intravenous infusion. '0.9% sodium chloride intravenous infusion' is the recommended solvent

Strength	Volume of Solvent (0.9% Sodium Chloride) (in ml)	Approximate concentration of Imipenem (mg/ml)
Imipenem/Cilastatin 500mg/500mg	100 ml	5mg/ml

Reconstitution of the 30 ml vial

The content of the vial must be suspended and transferred to 100 ml of an appropriate solution for infusion. A suggested procedure is to add approximately 10 ml of appropriate infusion solution to the vial. Shake well and transfer the resulting suspension to the infusion solution container.
Caution: the suspension is not for direct infusion.
Repeat with an additional 10 ml of infusion solution to ensure complete transfer of the vial contents to the infusion solution. The resulting mixture must be shaken until clear. Any unused medicinal product or waste material should be disposed of in accordance with local requirement.

7. Marketing authorization holder and manufacturing site address

Marketing authorization holder:

Company name: INNOCIA LIFESCIENCES PVT LTD
Address: Block A, No. 12, Balaji Nagar,
Ambattur, Chennai 600053,
Country: INDIA.
Telephone: +91 44 2658 5855
E-Mail: innocia1997@gmail.com

Manufacturing Site address:

Company Name: Zeiss Pharmaceuticals Pvt. Ltd.
Address: 72 Export promotion Industrial Park
Phase –I Jharmajri, Baddi Distt. Solan (H.P.)
Mob. No: 9218548704
E-mail : **qualitycontrol@zpharma.co.in**

8. Marketing authorization number

CTD12612

9. Date of first registration / renewal of the registration

23/07/2026

10. Date of revision of the text

23/07/2026