Imilan™ P1512386

Imilan™ P1512386

60 mm

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

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Imipenem and cilastatin injection IP 500 mg

Imilan™

Composition:

IMILAN

Each vial contains:
Imipenem IP (Sterile) equivalent to anhydrous Imipenem 500 mg.
Cilastatin Sodium IP (Sterile) equivalent to Cilastatin 500 mg
Sodium Bicarbonate IP (Sterile) as a buffer

DESCRIPTION:

IMILAN is a sterile formulation of imipenem (a thienamycin antibiotic)
and cilastatin sodium (the inhibitor of the renal dipeptidase, dehydropeptidase I) with sodium bicarbonate added as buffer. IMILAN (Imipenem and Cilastatin Injection) is a potent broad-spectrum antibacterial agent for intravenous administration.

INDICATIONS:

IMILAN (imipenem and cilastatin for injection) is indicated For the treatment of serious lower respiratory tract infections, urinary tract infections, intra-abdominal, bone and joint infection, endocarditis and bacterial septicemia, skin and skin structure infections

CONTRAINDICATION:

Contraindicated in patients who have shown hypersensitivity to any component of this product.

DOSE AND METHOD OF ADMINISTRATION[1]

Adults
The dosage recommendations for IMILAN (imipenem and cilastatin for injection) represent the quantity of imipenem to be administered. An equivalent amount of cilastatin is also present in the solution. Each 125 mg, 250 mg, or 500 mg dose should be given by intravenous administration over 20 to 30 minutes (Doses less than or equal to 500 mg should be given by intravenous infusion over 20 to 30 minutes.

Each 750 mg or 1000 mg dose should be infused over 40 to 60 minutes. In patients who develop nausea during the infusion, the rate of infusion may be slowed. (Doses greater than 500 mg should be given by intravenous infusion over 40 to 60 minutes).

The total daily dosage for intravenous imipenem-cilastatin should be based on the type or severity of infection and given in equally divided doses based on consideration of degree of susceptibility of the pathogen(s), renal function, and body weight. Adult patients with impaired renal function, as judged by creatinine clearance ≤ 70 mL/min/1.73 m2, require adjustment of dosage as described below.

Intravenous dosage schedule for adults with normal renal function and body weight ≥ 70 kg.
Doses cited in Table I are based on a patient with normal renal function and a body weight of 70 kg. These doses should be used for a patient with a creatinine clearance of ≥ 71 mL/min/1.73 m2 and a body weight of ≥ 70 kg. A reduction in dose must be made for a patient with a creatinine clearance of ≤ 70 mL/min/1.73 m2 and/or a body weight less than 70 kg (see Tables II and III).

Dosage regiments in column A to Table I are recommended for infections caused by fully susceptible organisms which represent the majority of pathogenic species. Dosage regimens in column B of Table I are recommended for infections caused by organisms with moderate susceptibility to imipenem, primarily some strains of P. aeruginosa.

Table I: Intravenous dosage schedule for adults with normal renal function (creatinine clearance ≥ 71mL/min/1.73 m2) and body weight ≥ 70 kg

Type or severity of Infection	A Fully susceptible organisms including gram-positive and gram-negative aerobes and anaerobes.	B Moderately susceptible organisms, primarily some strains of P. aeruginosa
Mild	250 mg q6h (Total Daily Dose = 1.0g)	500 mg q6h (Total Daily Dosage = 2.0g)
Moderate	500 mg q8h (Total Daily Dose = 1.5g) Or 500 mg q6h (Total Daily Dose = 2.0g)	500 mg q6h (Total Daily Dose = 2.0g) Or 1g q8h (Total Daily Dose = 3.0g)
Severe, life threatening only	500 mg q6h (Total Daily Dose = 2.0g)	1 g q8h (Total Daily Dose = 3.0g) Or 1 g q8h (Total Daily Dose = 4.0g)
Uncomplicated urinary tract infection	250 mg q6h (Total Daily Dose = 1.0g)	250 mg q6h (Total Daily Dose = 1.0g)
Complicated urinary	500 mg q6h Total Daily Dose = 2.0g)	500 mg q6h (Total Daily Dose = 2.0g)

Due to the high antimicrobial activity of intravenous imipenem-cilastatin, it is recommended that the maximum total daily dosage not exceed 50 mg/kg/day or 4.0 g/day, whichever is lower. There is no evidence that higher doses provide greater efficacy. However, patients over twelve years of age with cystic fibrosis and normal renal function have been treated with intravenous imipenem-cilastatin at doses up to 90 mg/kg/day in divided doses, not exceeding 4.0g/day.

Reduced intravenous schedule for adults with impaired renal function and/or body weight ≤ 70 kg.
Patients with creatinine clearance of ≤ 70 mL/min/1.73 m 2 and/or body weight less than 70 kg required dosage reduction if IMILAN (imipenem-cilastatin injection) as indicated in the tables below. Creatinine clearance may be calculated from serum creatinine concentration by the following equation.

$$\text{Clcr (Males)} = \frac{\text{(Wt.in kg) (140-age)}}{\text{(72) (Creatinine in mg/dL}}$$

Clcr (Females) = 0.85 x above value

To determine the dose for adults with impaired renal function and/or reduced body weight.

1. Choose a total daily dose from Tablet I based on infection characteristics.
2. a) If the total daily dose is 1.0 g, 1.5 g, or 2.0 g, use the appropriate subsection of Table II and continue with step 3.
   b) If the total daily dose is 3.0 g or 4.0 g, use the appropriate subsection of Tablet II and continue with step 3.
3. From Table II or III:
   a) Select the body weight on the far left which is closest to the patient's body weight (kg).
   b) Select the patient's creatinine clearance category.
   c) Where the row and column intersect is the reduced dosage regimen.

Table II: Reduced intravenous dosage of intravenous imipenem-cilastatin in adult patients with impaired renal function (creatinine clearance ≤ 70 mL/min/1.73 m²) and/or body weight < 70 kg.

And Body Weight (kg) is:	If Total Daily Dose from Table I is:											
	1.0 g/day				1.5 g/day				1.5 g/day			
	And creatinine clearance (mL/min/1.73 m²) is:				And creatinine clearance (mL/min/1.73 m²) is:				And creatinine clearance (mL/min/1.73 m²) is:			
	≥ 71	41-70	21-40	6-20	≥ 71	41-70	21-40	6-20	≥ 71	41-70	21-40	6-20
	Reduced dosage regimen (mg) is				Reduced dosage regimen (mg) is				Reduced dosage regimen (mg) is			
≥70	250 q6h	250 q8h	250 q12h	250 q12h	500 q8h	250 q6h	250 q8h	250 q12h	500 q8h	500 q8h	250 q6h	250 q12h
60	250 q8h	125 q6h	250 q12h	250 q12h	250 q6h	250 q8h	250 q8h	250 q12h	500 q8h	250 q6h	250 q8h	250 q12h
50	125 q6h	125 q6h	125 q8h	250 q12h	250 q6h	250 q8h	250 q12h	250 q12h	250 q6h	250 q6h	250 q8h	250 q12h
40	125 q6h	125 q8h	125 q12h	250 q12h	250 q8h	125 q6h	125 q8h	125 q12h	250 q6h	250 q8h	250 q12h	250 q12h
30	125 q8h	125 q8h	125 q12h	250 q12h	125 q6h	125 q8h	125 q8h	125 q12h	250 q8h	125 q6h	125 q8h	125 q12h

Table III: Reduced intravenous dosage of intravenous imipenem-cilastatin in adult patients with impaired renal function (creatinine clearance ≤ 70 mL/min/1.73 m²) and/or body weight < 70 kg.

And Body Weight (kg) is:	If Total Daily Dose from Table I is:							
	3.0 g/day				4.0 g/day			
	And creatinine clearance (mL/min/1.73 m²) is:				And creatinine clearance (mL/min/1.73 m²) is:			
	≥ 71	41-70	21-40	6-20	≥ 71	41-70	21-40	6-20
	Reduced dosage regimen (mg) is				Reduced dosage regimen (mg) is			
≥70	1000 q8h	500 q6h	500 q8h	500 q12h	1000 q6h	750 q8h	500 q6h	500 q12h
60	750 q8h	500 q8h	500 q8h	500 q12h	1000 q8h	750 q8h	500 q8h	500 q12h
50	500 q8h	500 q8h	250 q6h	250 q12h	750 q8h	500 q6h	500 q8h	500 q12h
40	500 q8h	250 q6h	250 q8h	250 q12h	500 q6h	500 q8h	250 q6h	250 q12h
30	250 q6h	250 q8h	250 q8h	250 q12h	500 q8h	250 q6h	250 q8h	250 q12h

Patients with **creatinine clearances of 6 to 20 mL/min/1.73 m²** should be treated with intravenous imipenem-cilastatin 125 mg or 250 mg every 12 hours for most pathogens. There may be an increased risk of seizures when doses of 500 mg every 12 hours are administered to these patients.

Patients with creatinine clearance ≤5 mL/min/1.73 m2 should not receive intravenous imipenem-cilastatin unless hemodialysis is instituted within 48 hours. There is inadequate information to recommend usage of intravenous imipenem-cilastatin for patients undergoing **peritoneal dialysis**.

Hemodialysis
When treating patients with **creatinine clearances of ≤ 5mL/min/1.73 m2 who are undergoing hemodialysis**, use the dosage recommendations for patients with creatinine clearances of 6-20 mL/min/1.73 m2 (See Table II and Table III). Both imipenem and cilastatin are cleared from the circulation during hemodialysis. The patient should receive intravenous imipenem-cilastatin after hemodialysis and at 12 hour intervals timed from the end of that hemodialysis session. **Dialysis patients, especially those with background CNS disease, should be carefully monitored; for patients on hemodialysis, intravenous imipenem-cilastatin is recommended only when the benefit outweighs the potential risk of seizures**.

Pediatrics:
For pediatric patients ≥ 3 months of age, the recommended dose for non-CNS infections is 15-25 mg/kg/dose administered every six hours. Based on studies in adults, the maximum daily dose for treatment of infections with fully susceptible organisms is 2.0 g per day, and of infections with moderately susceptible organisms (primarily some strains of P. aeruginosa) is 4.0 g/day. Higher doses (up to 90 mg/kg/day in older children) have been used in patients with cystic fibrosis.

For pediatric patients ≤ 3 months of age (weighing ≥ 1,500 grams), the following dosage schedule is recommended for non- CNS infections:
< 1 week of age: 25 mg/kg every 12 hrs.

1-4 weeks of age: 25 mg/kg every 9 hrs.

4 weeks-3 months of age: 25 mg/kg every 6 hrs.

Doses less than or equal to 500 mg should be given by intravenous infusion over 15 to 30 minutes. Doses greater than 500 mg should be given by intravenous infusion over 40 to 60 minutes.

Intravenous imipenem-cilastatin is not recommended in pediatric patients with **CNS infections because of the risk of seizures**.

Intravenous imipenem-cilastatin is not recommended in **pediatric patients <30 kg with impaired renal function, as no data are available**.

WARNINGS AND PRECAUTIONS:

• Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in-patients receiving therapy with beta-lactams • Before initiating therapy with imipenem-cilastatin, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, other beta-lactams, and other allergens • Seizure and other CNS adverse experiences, such as confusional states and myoclonic activity have been reported during treatment with imipenem & cilastatin injection
• Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including imipenem & cilastatin injection, and may range in severity from mild diarrhea to fatal colitis

ADVERSE REACTIONS:

Intravenous imipenem-cilastatin generally well tolerated. The most frequently reported systemic adverse clinical reactions that were reported as possibly, probably, or definitely reported to intravenous imipenem-cilastatin were nausea (2.0%), diarrhea (1.8%), vomiting (1.5%), rash (0.9%), fever (0.5%), hypotension (0.4%), seizures (0.4%) (see PRECAUTIONS), dizziness (0.3%), pruritus (0.3%), urticaria (0.2%), somnolence (0.2%).

FRONT SIDE

ARTWORK DETAIL LABEL

Product	**Imilan 500 mg**		
Buyer/Country	Mylan / India	Component	Pack Insert
Dimension	240 x 410 mm	Pack	--
New Item Code	P1512386	Old Item Code	NA
Colour Shades	Black	No. of Colours	1

Change Control No.	NA
Design/Style	Front & Back Printing. To be supplied in the booklet size XX x XX mm
Substrate	40/45 GSM Paper.
Special Instructions	Printing clarity to be clear & sharp.
Autocartonator Requirements	NA

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. **DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.**

60 mm

USE IN SPECIAL POPULATIONS[1]

- **Pregnancy**
  No evidence of adverse effect on the fetus has been reported in teratogenic studies in rabbits (IV dose up to 300 mg/kg/day) and rat (SC dose up to 1000 mg/kg/day). There are, however, no adequate and well-controlled studies in pregnant women. Imipenem-cilastatin should be used during pregnancy only if the potential benefit justifies the potential risk to the mother and fetus (see PRECAUTIONS: Pregnancy).
- **Lactation**
  It is not known whether imipenem-cilastatin sodium is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when imipenem-cilastatin is administered to a nursing woman.
- **Pediatrics**
  Use of intravenous imipenem-cilastatin in pediatric patients, neonates to 16 years of age, is supported by evidence from adequate and well-controlled studies of intravenous imipenem-cilastatin in adults and by the clinical studies and published literature in pediatric patients.

  Intravenous imipenem-cilastatin is not recommended in pediatric patients <30 kg with impaired renal function, as no data are available (see PRECAUTIONS: Pediatrics).
- **Geriatrics**
  No overall differences in safety or effectiveness between elderly subjects (≥ 65 years) and younger subjects have been reported. However, a greater sensitivity of some older individuals cannot be ruled out. This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Directions for Use

• Vials

These are the vials which have a capacity of approximately 30 ml.

Contents of the vials must be suspended and transferred to 100 mL of an appropriate infusion solution. A suggested procedure is to add approximately 10 mL from the appropriate infusion solution (see list of diluents under **COMPATIBILITY AND STABILITY**) to the vial. Shake well and transfer the resulting suspension to the infusion solution container. For detailed information see **INSTRUCTIONS FOR USE**.

CAUTION: THE SUSPENSION IS NOT FOR DIRECT INFUSION.

Repeat with an additional 10 mL of infusion solution to ensure complete transfer of vial contents to the infusion solution. **The resulting mixture should be agitated until clear**.

INSTRUCTIONS FOR USE OF IMILAN

For IMILAN supplied as single use vials of 30 ml capacity.

VIAL (30 ml capacity)

- Examine the vials for any foreign material in the powder and make sure that the tamper-evident seal between the cap and the container is intact.
- Do not use the pack if any foreign particle is present or the seal of the container is not intact.
- Use aseptic technique for preparing solution for infusion.

Method of Reconstitution:

1. Remove the flip off cap to break off seal from the vial
2. Add 10 ml of diluent (see Compatibility and Stability)
3. Shake the vial to constitute the powder.
4. Transfer the reconstituted suspension in IV bag/bottle.
5. Add an additional 10 ml of diluent in the vial, shake well and transfer the contents in IV bag/bottle.
6. Mix the contents thoroughly before use within the specified time.

COMPATIBILITY AND STABILITY

IMILAN, as supplied in single use vials, and reconstituted with the following diluents, maintains satisfactory potency for 4 hours at room temperature (25°C) or for 24 hours under refrigeration (5°C). Solutions of IMILAN should not be frozen.

- Sodium Chloride Injection 0.9% w/v.
- Dextrose Injection 5% w/v or 10% w/v.
- Dextrose 5% w/v and Sodium Chloride Injection 0.9% w/v
- Dextrose Injection 5% w/v with Saline Solution 0.225% w/v or 0.45% w/v. - Dextrose Injection 5% w/v with Potassium Chloride Solution 0.15% w/v.
- Mannitol Injection 5% w/v or 10% w/v.

IMILAN should not be mixed with or physically added to other antibiotics. However, IMILAN may be administered concomitantly with other antibiotics, such as aminoglycosides.

- Before reconstitution: The dry powder should be stored at a temperature below 25°C (77°F).
- After reconstitution: Solution of IMILAN range from colourless to yellow. Variation of colour within this range do not affect potency of the product.

PHARMACODYNAMIC AND PHARMACOKINETIC PROPERTIES[1]

- **Mechanism of Action**

The bactericidal activity of imipenem results from the inhibition of cell wall synthesis. Its greatest affinity is for penicillin-binding protein (PBPs) 1A, 1B, 2, 4, 5 and 6 of *Escherichia coli*, and 1A, 1B, 2, 4 and 5 of *Pseudomonas aeruginosa*. The lethal effect is related to binding to PBP 2 and PBP 1B. Imipenem has a high degree of stability in the presence of beta-lactamases, including penicillinases and cephalosporinases produced by gram-negative and gram-positive bacteria. It is a potent inhibitor of betalactamases from certain gram-negative bacteria, which are inherently resistant to many beta-lactam antibiotics, e.g., *Psudomonas aeruginosa, Serratia spp. and Enterobacter* spp.

Imipenem, when administered alone, is metabolized in the kidneys by dehydropeptidase I resulting in relatively low levels in urine, Cilastatin sodium an inhibitor of this enzyme, effectively prevents renal metabolism of imipenem so that when imipenem and cilastatin sodium are given concomitantly, fully adequate antibacterial levels of imipenem are achieved in the urine.

Cilastatin sodium is devoid of intrinsic antibacterial activity itself and does not affect the antibacterial activity of imipenem.

Antimicrobial spectrum

Imipenem has in vitro activity against a wide range of gram-positive and gram-negative organisms.

Imipenem has been shown to be active against most strains of the following microorganisms both *in vitro* and in clinical infections treated with imipenem-cilastatin sodium intravenous formulation.

Gram-positive aerobes: Enterococcus faecalis (formerly S. Faecalis) (imipenem is inactive *in vitro* again *Enterococcus faecium [formerly S. Faecium]), Staphylococcus aureus* including penicillinase-producing strains, *Staphylococcus epidermidis* including penicillase-producing strain (Methicillin-resistant staphylococcui should be reported as resistant to imipenem), *Streptococcus agalactiae (Group B streptococci), Streptococcus pneumonia, Streptococcus pyogenes.*

G*ram-negative aerobes: Acinetobacter spp., Citrobacter spp., Enterobacter spp., Escherichia coli, Gardnerella vaginalis, Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella spp., Morganella morganii, Proteus vulgaris, Providencia rettgeri, Pseudomonas aeruginosa (imipenem is inactive in vitro against Xanthomonas (Pseudomonas) maltophilia and some strains of P. cepacia.), Serratia spp.* including *S. Marcescens.*

Gram-negative anaerobes: Bifidobacterium spp., *Clostridium* spp., *Eubacterium* spp., *Peptococcus* spp., *Peptostreptococcus* spp., *Propionibacterium* spp.

Gram-negative anaerobes: Bacteroides spp. including *B. Fragilis*, *Fusobacterium* spp.

The following *in vitro* data are available, **but their clinical significance is unknown**.

Imipenem exhibits *in vitro* minimum inhibitory concentrations (MICs) of 4 g/mL or less again most (≥ 90%) strains of the following microorganisms; however, the safety and effectiveness of imipenem in treating clinical infections due to these microorganisms have not been established in adequate and well-controlled clinical trials.

Gram-positive aerobes: Bacilius spp., *Listeria monocytogenes, Nocardia* spp., *Staphylococcus saprophyticus, Group C streptococci, Group G streptococci, Viridans group streptococci.*

Gram-negative aerobes: Aeromonas hydrophila, Alcaligenes spp., Capnocytophaga spp., Haemophilus ducreyi, Neisseria gonorrhoeae including penicillinase-producing strains, Pasteurella spp., Providencia stuartii.

Gram-negative anaerobes: Prevotella bivia, Prevotella disiens, Prevotella melaninogenica, Veillonella spp.

In vitro tests show imipenem to act synergistically with aminoglycoside antibiotics against some isolates of *Pseudomonas aeruginosa.*

- **Pharmacokinetics**

Adults

Intravenous administration

Intravenous infusion of imipenem-cilastatin over 20 minutes results in peak plasma levels of imipenem antimicrobial activity that range from 14 to 24 µg/mL for the 250 mg dose, from 21 to 58 µg/mL for the 500 mg dose, and from 41 to 83 µg/mL for the 1000 mg dose. At these doses, plasma levels of imipenem antimicrobial activity decline to below 1 µg/mL or less in 4 to 6 hours. Peak plasma levels of cilastatin following a 20-minute intravenous infusion of imipenem-cilastatin, range from 15 to 25 µg/mL for the 250 mg dose, from 31 to 49 µg/mL for the 500 mg dose, and from 56 to 88 g/mL for the 1000 mg dose.

The plasma half-life of each component is approximately 1 hour. The binding of imipenem to human serum proteins is approximately 20% and that of cilastatin is approximately 40%. Approximately 70% of the administered imipenem is recovered in the urine within 10 hours after which no further urinary excretion is detectable. Urine concentrations or imipenem in excess of 10 µg/mL can be maintained for up to 8 hours with intravenous imipenem -cilastatin at the 500 mg dose. Approximately,70% of the cilastatin sodium dose is recovered in the urine within 10 hours of administration of intravenous imipenem-cilastatin.

No accumulation of imipenem-cilastatin in plasma or urine is observed with regimens administered as frequently as every 6 hours in patients with normal renal function.

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-lives of imipenem and cilastatin are 91 ± 7.0 minutes and 69 ± 15 minutes, respectively. Multiple dosing has no effect on the pharmacokinetics of either imipenem or cilastatin, and no accumulation of imipenem-cilastatin is observed.

After a 1 gram dose of imipenem-cilastatin administered intravenously, measurable levels of imipenem were found in various tissues and fluids including vitreous humor, aqueous humor, lung tissue, sputum pleural fluid, peritoneal fluid, bile, CSF (uninflamed), CSF (inflamed), fallopian tubes, endometrium myometrium, bone, interstitial fluid, skin and fascia.

Imipenem-cilastatin sodium is hemodialyzable. However, usefulness of this procedure in the overdosage setting is questionable.

INCOMPATIBILITIES

Imipenem-cilastatin is chemically incompatible with lactate and should not be reconstituted with diluents 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 with, or physically added to other antibiotics.

SHELF LIFE:

Before reconstitution: Not more than 24 months

STORAGE:

The dry powder should be stored below 25°C, protected from moisture.

The reconstituted solution should be used within 4 hours (if stored at temperature upto 25°C) or 24 hours if stored under refrigeration (5°C). Solution of IMILAN-500 should not be frozen.

PRESENTATION:

IMILAN is supplied as a sterile powder mixture in single dose containers containing Imipenem (anhydrous equivalent) and cilastatin sodium along with Sodium Bicarbonate added as buffer.

IMILAN-500 is available in clear glass vial with rubber stoppers and aluminium collar seals with plastic flip-off tops. IMILAN-500 is available in vial size of 30 ml.

REFERENCES

1. Prescribing information of PRIMAXIN, Merck & Co., Whitehouse Stations, NJ 088889 USA. December 2007.
2. Product monograph: Cilastatin sodium USP.
3. Ahonkhai VI et al (1989). Imipenem-cilastatin in pediatric patients: an overview of safety and efficacy in studies conducted in the United States. Pediatric Infect Dis J 8(11): 740-4.

Mylan

Manufactured by:
Auronext Pharma Pvt. Ltd.
A-1128, RIICO Industrial Area, Phase-III,
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Rajasthan, India.

Marketed by:
Mylan Pharmaceuticals Private Limited
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Raigad (Dist), Maharashtra - 410 208,
INDIA.

TM - Trade Mark under registration
Mfg. Lic. No.: RAJ - No. 2405

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BACK SIDE

ARTWORK DETAIL LABEL

Product	**Imilan 500 mg**				
Buyer/Country	Mylan / India	Component	Pack Insert		
Dimension	240 x 410 mm			Pack	--
New Item Code	P1512386	Old Item Code	NA		
Colour Shades	Black			No. of Colours	1

Change Control No.	NA
Design/Style	Front & Back Printing. To be supplied in the booklet size XX x XX mm
Substrate	40/45 GSM Paper.
Special Instructions	Printing clarity to be clear & sharp.
Autocartonator Requirements	NA

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