For the use of a Registered Medical Practitioner Only

1.GENERIC NAME AND BRND NAME
Linezolid Tablets I.P. 600mg
Linoplus™

2.QUALITATIVE AND QUANTITATIVE COMPOSITION
Each film coated tablet contains:
Linezolid I.P 600mg
Excipients q.s.
Colour: Titanium Dioxide I.P.

3.DOSAGE FORM AND STRENGTH
Refer section 1 & 2

4.CLINICAL PARTICULARS
4.1 THERAPEUTIC INDICATION
1. For osteomyelitis in adults
2. For Complicated/uncomplicated skin & skin structure infection, community acquired pneumonia

4.2 POSOLOGY AND METHOD OF ADMINISTRATION
The recommended dosage for Linezolid formulations for the treatment of infections is described below:

infection*	**Dosage and Route of Administration**		**Recommended Duration of Treatment (consecutive days)**
	Pediatric Patients† (Birth through 11 Years of Age)	**Adults and Adolescents (12 Years and Older)**	
Nosocomial pneumonia Community-acquired pneumonia, including concurrent bacteremia Complicated skin and skin structure infections	10 mg/kg intravenously or oral‡ every 8 hours	600 mg intravenously or oral‡ every 12 hours	10 to 14
Vancomycin-resistant Enterococcus faecium infections, including concurrent bacteremia	10 mg/kg intravenously or oral‡ every 8 hours	600 mg intravenously or oral‡ every 12 hours	14 to 28
Uncomplicated skin and skin structure infections	less than 5 yrs: 10 mg/kg oral‡ every 8 hours 5-11 yrs: 10 mg/kg oral* every 12 hours	Adults: 400 mg oral‡ every 12 hours Adolescents: 600 mg oral‡ every 12 hours	10 to 14
* Due to the designated pathogens † Neonates less than7 days: Most pre-term neonates less than7 days of age (gestational age less than34 weeks) have lower systemic linezolid clearance values and larger AUC values than many full-term neonates and older infants. These neonates should be initiated with a dosing regimen of 10 mg/kg every 12 hours. Consideration may be given to the use of 10			

mg/kg every 8 hours regimen in neonates with a sub-optimal clinical response. All neonatal patients should receive 10 mg/kg every 8 hours by 7 days of life ‡ Oral dosing using either Linezolid Tablets or Linezolid for Oral Suspension

When switching from intravenous to oral administration, no dose adjustment is necessary.

Intravenous Administration

Prior to administration, parenteral drug, the products should be inspected visually for particulate matter. Protect linezolid injection from freezing by storing it at the room temperature. Over time Injection may exhibit a yellow color that can intensify without adversely affecting potency.

Linezolid Injection should be administered by intravenous infusion over a period of 30 to 120 minutes.
If Linezolid Injection is to be co-administered with another drug, in accordance with the recommended dosage, each drug should be given separately
For sequential infusion of several drugs, if the same intravenous line is used, the line should be flushed before and after infusion of Linezolid Injection with an infusion solution compatible with LinezolidInjection and with any other drug(s) administered via this common line.

Compatibilities
Compatible intravenous solutions include 5% Dextrose Injection, 0.9% Sodium Chloride Injection, USP, USP, and Lactated Ringer's Injection, USP.

Incompatibilities
Physical incompatibilities resulted when Linezolid I.V. Injection was combined with the following drugs during simulated Y-site administration: diazepam, chlorpromazine HCl, amphotericin B, erythromycinlactobionate, pentamidineisothionate, phenytoin sodium, and trimethoprim-sulfamethoxazole.
When Linezolid I.V. Injection was combined with ceftriaxone sodium, additionally, chemical incompatibility was found.

4.3 CONTRAINDICATIONS

Contraindicated in patients with

- Known hypersensitivity to linezolid or to any excipients of product
- Monoamine Oxidase Inhibitors: Linezolid must not be used concomitantly in patients taking any drug which inhibits monoamine oxidases A or B (e.g., phenelzine, isocarboxazid) or within two weeks of taking any such medicinal product
- Potential Interactions Producing Elevation of Blood Pressure Linezolid must not be administered to patients with uncontrolled hypertension, pheochromocytoma, thyrotoxicosis and/or patients taking drugs such as directly and indirectly acting sympathomimetic agents (e.g., pseudoephedrine), vasopressive agents (e.g., epinephrine, norepinephrine), dopaminergic agents (e.g, dopamine, dobutamine)
- Potential Serotonergic Interactions Close monitoring of the patients is recommended for signs and/or symptoms of serotonin syndrome. Linezolid is contraindicated in patients with carcinoid syndrome and/or patients taking any of the following drugs: serotonin re-uptake inhibitors, tricyclic antidepressants, serotonin 5-HT1 receptor agonists (triptans), meperidine or buspirone.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Myelosuppression

In patients receiving linezolid, Myelosuppression (including thrombocytopenia, anemia, leukopenia, pancytopenia,) has been reported. These effects were reversed upon linezolid discontinuation

Complete blood counts should be monitored weekly especially in patients who receive linezolid for longer than two weeks, those receiving concomitant drugs that cause bone marrow suppression, those with pre-existing myelosuppression, or concomitant antibiotic therapy those with a chronic infection who have received previous or concomitant antibiotic therapy.

In patients who develop or have worsening myelosuppression, discontinuation of therapy with linezolid must be considered.

Peripheral and Optic Neuropathy

In patients treated with linezolid, peripheral and optic neuropathies progressing to progressed to loss of vision have been reported primarily in patients treated for longer than the maximum recommended duration of 28 days.

In some patients treated with linezolid for less than 28 days, visual blurring has been reported. In children peripheral and optic neuropathy has also been reported.

Immediate ophthalmic evaluation is recommended, if patients experience symptoms of visual impairment, such as changes blurred vision, visual acuity, changes in color vision, or visual field defect.

It is important to monitor the visual function in all patients taking linezolid for extended periods (≥ 3 months) and in all patients reporting new visual symptoms regardless of length of therapy with linezolid. The continued use of linezolid in these patients must be weighed against the potential risks, if peripheral or optic neuropathy occurs.

Serotonin Syndrome

Concomitant use of linezolid , serotonergic agents and selective serotonin reuptake inhibitors (SSRIs) has been associated with spontaneous reports of serotonin syndrome including fatal cases have been reported.

Unless clinically appropriate and patients are carefully observed for signs and/or symptoms of neuroleptic malignant syndrome-like (NMS-like) reactions or serotonin syndrome, linezolid should not be administered to patients with carcinoid syndrome and/or patients taking any of the following medications: tricyclic antidepressants, serotonin 5-HT1 receptor agonists (triptans), serotonin re-uptake inhibitors, meperidine, bupropion, or buspirone.

Patients may require urgent treatment with linezolid, in a few cases such as if a patient is already receiving a serotonergic antidepressant or buspirone. In these patients administer linezolid only if the potential benefits of linezolid outweigh the risks of serotonin syndrome or NMS-like reactions and if alternatives to linezolid are not available. The serotonergic antidepressant should be stopped immediately and linezolid must be administered.

If concomitant treatment with duloxetine and other agents that may affect the serotonergic and/or dopaminergic neurotransmitter systems is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases.

The patient should be monitored for two weeks (five weeks if fluoxetine was taken) or until 24 hours after the last dose of linezolid, whichever comes first.

Symptoms of serotonin syndrome or NMS-like reactions include autonomic instability, hyperthermia, rigidity, myoclonus, and mental status changes that include coma and extreme agitation progressing to delirium.The patient should also be monitored for discontinuation symptoms of the antidepressant.

Mortality Imbalance in Patients With Catheter-Related Bloodstream Infections, Including Those With Catheter-Site Infections

Linezolid has not been approved and must not be used for the treatment of patients with catheter-related bloodstream infections or catheter-site infections. Linezolid is not indicated for the treatment of Gram-negative infections as it has no clinical activity against Gram-negative pathogens. If a concomitant Gram-negative pathogen is documented or suspected, it is critical that specific Gram-negative therapy be initiated promptly.

Clostridium Difficile Associated Diarrhea

As with use of nearly all antibacterial agents, including linezolid, Clostridium difficile associated diarrhea (CDAD) has been reported ranging in severity from mild diarrhea to fatal colitis. The altered normal flora of colon after antibacterial treatment may permit overgrowth of C. difficile.

Development of CDAD is due to toxins A and B which produced by C. difficile. Strains of C. difficile producing hypertoxin causes increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. Following antibiotic use, CDAD must be considered in all patients who have diarrhea. Since CDAD has been reported to occur over two months after the administration of antibacterial agents, careful medical history is necessary.

Ongoing antibiotic use not directed against C. difficile may need to be discontinued if CDAD is suspected or confirmed. Appropriate protein supplementation, fluid and electrolyte management, antibiotic treatment of C. difficile, and surgical evaluation must be administered.

Potential Interactions Producing Elevation of Blood Pressure

Linezolid should not be administered, unless patients are monitored for potential increases in blood pressure, and to the patients with uncontrolled hypertension, thyrotoxicosis pheochromocytoma, and/or patients taking any of the following drugs: directly and indirectly acting sympathomimetic agents (e.g., pseudoephedrine), dopaminergic agents (e.g., dopamine,dobutamine), vasopressive agents (e.g., epinephrine, norepinephrine).

Lactic Acidosis

With the use of linezolid, lactic acidosis has been reported. In reported cases, patients experienced repeated episodes of nausea and vomiting. Patients who develop recurrent nausea or vomiting, a low bicarbonate level or unexplained acidosis, should receive immediate medical evaluation when under treatment with linezolid. .

Convulsions

Linezolid has been reported to cause seizures in patients with a history of seizures or risk factors for seizures.

Hypoglycemia

When treated with linezolid, a reversible, nonselective MAO inhibitor, symptomatic hypoglycemia has been reported in patients with diabetes mellitus receiving insulin or oral hypoglycemic agents.

In diabetic patients receiving insulin or hypoglycemic agents, some MAO inhibitors have been associated with hypoglycemic episodes. While a causal relationship between linezolid and hypoglycemia has not been established, diabetic patients should be cautioned of potential hypoglycemic reactions if they are treated with linezolid.

If hypoglycemia occurs, discontinuation of oral hypoglycemic agent, insulin, or a decrease in the dose of insulin or oral hypoglycemic agent, or or linezolid may be required.

Development of Drug-Resistant Bacteria

Prophylactic use of linezolid or use of linezolid in the patient with no proven gram positive bacterial infection,increases the risk of the development of drug-resistant bacteria.

Nonclinical Toxicology

Carcinogenesis, Mutagenesis, Impairment of Fertility

There are no animal studies conducted to evaluate the carcinogenic potential of linezolid, Neither mutagenic nor clastogenic potential was found in a battery of tests .

Linezolid did not affect the fertility or reproductive performance in female rats. When given at doses ≥ 50 mg/kg/day,linezolid reversibly decreased fertility and reproductive performance in adult male rats with exposures comparable to or greater than the expected human exposure level .

Mild decrease in fertility was observed in sexually mature male rats exposed to linezolid as juveniles, through most of their period of sexual development.With shorter treatment periods, decreased fertility was not observed.

In rats treated from postnatal day 22 to 35, reversible reductions in sperm motility and altered sperm morphology were observed.

Use In Specific Populations

Pregnancy
Teratogenic Effects
Pregnancy Category C

In mice, rats, or rabbits, Linezolid was not teratogenic at exposure levels 6.5-fold (in mice), equivalent to (in rats), or 0.06-fold (in rabbits) the expected human exposure level. However, fetal and embryo toxicities were seen. There are no adequate and well-controlled studies in pregnant women.Linezolid must not be administered to pregnant women unless the potential benefits to the mother justifies the risk to the fetus.

Non-teratogenic Effects

At doses that caused maternal toxicity (clinical signs and reduced body weight gain), in mice, only embryo and fetal toxicities were seen. At 15 and 50 mg/kg/day in rats, mild fetal toxicity was observed.

The effects consisted of reduced ossification of sternebrae and decreased fetal body weights and, a finding often seen in association with decreased fetal body weights.
During pregnancy and lactation, when female rats were treated with 50 mg/kg/day of linezolid, on postnatal days 1 to 4, survival of pups was decreased. When mated, male and female pups permitted to mature to reproductive age, showed an increase in preimplantation loss.

Nursing Mothers
Linezolid and its metabolites are excreted in the milk of lactating rats but there is no data regarding its excretion in human milk. Caution should be exercised when linezolid is administered to a nursing woman because many drugs are excreted in human milk.

Pediatric Use
Currently there is limited data on the pharmacokinetic data of linezolid during multiple dosage of pediatric patients of all ages. Pharmacokinetic data indicates that patients dosed with 10mg/kg have a similar C_{max}, but a higher average clearance when corrected by body weight and shorter elimination half-life as comared to adults.

Geriatric Use
There is no difference in the efficacy and safety of linezolid in elderly patients as compared to young patients.

4.5 DRUG INTERACTION

No.	Drug	Drug Interaction	Remarks
1.	**Monoamine Oxidase Inhibition**	Linezolid has the potential for interaction with adrenergic and serotonergic agents as Linezolid is a reversible, nonselective inhibitor of monoamine oxidase.	
2.	**Adrenergic Agents**	In normal adult subjects receiving linezolid and tyramine doses of more than 100 mg, a significant pressor response has been observed.	Patients receiving linezolid with high tyramine content need to avoid consuming large amounts of foods or beverages.
3.	**Serotonergic Agents**	No serotonin syndrome effects (diaphoresis, confusion, restlessness, delirium, tremors, blushing, hyperpyrexia) have been observed in normal subjects receiving dextromethorphan and linezolid	
4.	**Aztreonam**	When administered together the pharmacokinetics of linezolid or aztreonam is not altered.	

5.	**Gentamicin**	When administered together the pharmacokinetics of linezolid or gentamicin is not altered	
6.	**Rifampin**	Concomitant use of rifampin with linezolid resulted in a 32% decrease in linezolid AUC0-12 and 21% decrease in linezolid C_{max} The mechanism of this interaction is not fully understood and may be related to the induction of hepatic enzymes.	
7.	**Drugs Metabolized by Cytochrome P450**	Linezolid is not an inducer of cytochrome P450 (CYP450). In addition, linezolid does not inhibit the activities of clinically significant human CYP isoforms (e.g., 1A2, 2C9, 2C19, 2D6, 2E1, 3A4). Therefore, linezolid is not expected to affect the pharmacokinetics of these drugs. (S)-warfarin, which is extensively metabolized by CYP2C9, concurrent administration of linezolid does not substantially alter the pharmacokinetic characteristics of (S)-warfarin.	No changes are required in dosage regimen of drugs such as warfarin and phenytoin, which are CYP2C9 substrates, when they are co administered with linezolid.
8.	**Tyramine**	A significant pressor response occurs in normal adult subjects receiving linezolid and tyramine doses of more than 100 mg.	Patients receiving linezolid must avoid consuming large amounts of foods or beverages with high tyramine content
9.	**Pseudoephedrine HCl or phenylpropanolamine HCl**	A reversible enhancement of the pressor response of either pseudoephedrine HCl (PSE) or phenylpropanolamine HCl (PPA) is observed when linezolid is administered to healthy normotensive subjects	

4.6 USE IN SPECIAL POPULATIONS (SUCH AS PREGNANT WOMEN, LACTATING WOMEN, PAEDIATRIC PATIENTS, GERIATRIC PATIENTS ETC.)

Pregnancy

Teratogenic Effects
Pregnancy Category C

In mice, rats, or rabbits, Linezolid was not teratogenic at exposure levels 6.5-fold (in mice), equivalent to (in rats), or 0.06-fold (in rabbits) the expected human exposure level. However, fetal and embryo toxicities were seen. There are no adequate and well-controlled studies in pregnant women. Linezolid must not be administered to pregnant women unless the potential benefit to the mother justifies the risk to the fetus.

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Linezolid and its metabolites are excreted in the milk of lactating rats but there is no data regarding its excretion in human milk. Caution should be exercised when linezolid is administered to a nursing woman because many drugs are excreted in human milk.

Pediatric Use
Currently there is limited data on the pharmacokinetic data of linezolid during multiple dosage of pediatric patients of all ages. Pharmacokinetic data indicates that patients dosed with 10mg/kg have a similar Cmax, but a higher average clearance when corrected by body weight and shorter elimination half-life as comared to adults.

Geriatric Use
There is no difference in the efficacy and safety of linezolid in elderly patients as compared to young patients.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
Patients should be warned about the potential for dizziness or symptoms of visual impairment whilst receiving linezolid and should be advised not to drive or operate machinery if any of these symptoms occur.

4.8 UNDESIRABLE EFFECTS
Nervous system: Headache, dizziness, vertigo, peripheral neuropathy, Convulsions
Respiratory:
Gastrointestinal: Taste alteration, tongue discoloration, superficial tooth discoloration oralmoniliasis, nausea, vomiting, generalized abdominal pain, diarrhea
Skin: Rash, Pruritus at non-application site, bullous skin disorders such as those described as Stevens-Johnson syndrome
Immunity: Fungal infection**,** Anaphylaxis, angioedema
Blood and lymphatics: Anemia, thrombocytopenia, leukopenia, eosinophilia

Genitourinary: Vaginal moniliasis
Endocrine: Hypoglycemia
Special senses: opticneuropathy, loss of vision
Laboratory tests: Abnormal liver function tests,

4.9 OVERDOSAGE
Presenting features of acute toxicity in ratswere decreased activity and ataxia and in dogs vomiting and tremors when treated with doses as high as 3000 mg/kg/day and 2000 mg/kg/day, respectively.
Treatment
Supportive care is advised, with maintenance of glomerular filtration in the event of overdosage, more rapid elimination of linezolid may be facilitated by hemodialysis. Approximately 30% of a dose of linezolid was removed during a 3-hour hemodialysis session beginning 3 hours after the dose of linezolid was administered. Currently there is no data regarding the removal of linezolid with peritoneal dialysis or hemoperfusion.

5.0 PHARMACOLOGICAL PROPERTIES
5.1 MECHANISM OF ACTION
Linezolid binds to a site on the bacterial 23S ribosomal RNA of the 50S subunit and prevents the formation of a functional 70S initiation complex, which is an essential component of the bacterial translation process. Linezolid thus inhibits bacterial protein synthesis by a different mechanism as compared to other antibacterial agents; therefore, it is unlikely to have cross resistance with other classes of antibiotics.

5.2 Pharmacodynamic Properties:
Linezolid is a synthetic antibacterial drug .it belongs to a new class of antibiotics, the oxazolidinones, which have clinical utility in the treatment of infections caused by aerobic Gram-positive bacteria. The in vitro spectrum of activity of linezolid also includes certain anaerobic bacteria and Gram-negative bacteria.
The results of time-kill studies have shown linezolid to be bacteriostatic against enterococci and staphylococci. Linezolid was found to be bactericidal for the majority of strains of Staphylococci and for Streptococci.
Linezolid has been shown to be active against most isolates of the following microorganisms, both in vitro and in clinical infections.

Gram-Positive Bacteria
Enterococcus faecium (vancomycin-resistant isolates only)
Staphylococcus aureus (including methicillin-resistant isolates)
Streptococcus agalactiae
Streptococcus pneumoniae
Streptococcus pyogenes
The safety and effectiveness of linezolid in treating clinical infections due to the bacteria have not been established in adequate and well-controlled clinical trials.

Gram-Positive Bacteria
Enterococcus faecalis (including vancomycin-resistant isolates)
Enterococcus faecium (vancomycin-susceptible isolates)
Staphylococcus epidermidis (including methicillin-resistant isolates)
Staphylococcus haemolyticus
Viridans group streptococci

5.3 Pharmacokinetic Properties

Pharmacokinetics

Parameters	Linezolid
Absorption	After oral dosing Linezolid is rapidly and extensively absorbed. Approximately 1 to 2 hours after dosing, maximum plasma concentrations are reached and the absolute bioavailability is approximately 100%. Therefore, without dose adjustment linezolid may be given orally or intravenously. Linezolid may be administered without regard to the timing of meals. When high fat food is given with linezolid, the time to reach the maximum concentration is delayed from 1.5 hours to 2.2 hours and Cmax is decreased by about 17%. However, the total exposure values measured as AUC0-∞ is similar under both conditions.
Distribution	Linezolid readily distributes to well-perfused tissues
Protein Binding	Linezolid plasma protein binding is approximately 31% and is concentration independent. The volume of distribution of linezolid at steady state is 40 to 50 liters.
Metabolism	The metabolic pathway of linezolid is not fully understood. Linezolid is minimally metabolized, and this may be mediated by human cytochrome P450 Linezolid is primarily metabolized by oxidation of the morpholine ring, resulting in two inactive ring-opened carboxylic acid metabolites: the aminoethoxyacetic acid metabolite (A), and the hydroxyethyl glycinemetabolite (B). Formation of metabolite A is presumed to be formed via an enzymatic pathway whereas by a non-enzymatic chemical oxidation mechanism in vitro metabolite B is mediated.
Excretion	Non-renal clearance accounts for approximately 65%. Approximately 30% of the dose appears in the urine as linezolid, 10% as metabolite A and 40% as metabolite B. Linezolid mean renal clearance is 40 mL/min which suggests net tubular reabsorption. Virtually no parent drug linezolid is excreted in the feces , while approximately 6% of the dose appears in the feces as metabolite B, and 3% as metabolite A.
Half Life	6.4 hours

Pharmacokinetics in special patient populations

Renal Impairment
The pharmacokinetics of the parent drug, linezolid, are not altered in patients with any degree of renal impairment. But the two primary metabolites of linezolid accumulate in patients with renal impairment, with the amount of accumulation increasing with the severity of renal impairment. No dose adjustment is recommended for patients with renal impairment.
Both linezolid and the two metabolites are eliminated by hemodialysis. Currently there is no data on the effect of peritoneal dialysis on the pharmacokinetics of linezolid. About 30% of a dose is eliminated in a 3-hour hemodialysis session beginning 3 hours after the dose of linezolid was administered; therefore, linezolid should be given after hemodialysis.

Hepatic Impairment
The pharmacokinetics of linezolid are not altered in patients with mild-to-moderate hepatic impairment. No dose adjustment is recommended for patients with mild-to-moderate hepatic impairment. The pharmacokinetics of linezolid in patients with severe hepatic impairment have not been evaluated.

6. NONCLINICAL PROPERTIES
6.1 ANIMAL TOXICOLOGY OR PHARMACOLOGY

Nonclinical Toxicology

Carcinogenesis, Mutagenesis, Impairment of Fertility
There are no animal studies conducted to evaluate the carcinogenic potential of linezolid, neither mutagenic nor clastogenic potential was found in a battery of tests.

Linezolid did not affect the fertility or reproductive performance in female rats. When given at doses ≥ 50 mg/kg/day, linezolid reversibly decreased fertility and reproductive performance in adult male rats with exposures comparable to or greater than the expected human exposure level.

Mild decrease in fertility was observed in sexually mature male rats exposed to linezolid as juveniles, through most of their period of sexual development. With shorter treatment periods, decreased fertility was not observed.

In rats treated from postnatal day 22 to 35, reversible reductions in sperm motility and altered sperm morphology were observed.

7. DESCRIPTION
LINOPLUS is supplied for oral administration, as a film coated tablet of Linezolid. Each film coated tablet of LINOPLUS contains Linezolid 600 mg.

8. PHARMACEUTICAL PARTICULARS
8.1 INCOMPATIBILITIES
Not Applicable

8.2 SHELF-LIFE
Refer pack

8.3 PACKAGING INFORMATION
Refer pack

8.4 STORAGE CONDITION AND HANDING INSTRUCTIONS
Refer pack

9. PATIENT COUNSELLING INFORMATION
Patients should be advised that:

- Linezolid oral may be taken with or without food.
- They should inform their physician if they have a history of hypertension.
- Large quantities of foods or beverages with high tyramine content should be avoided while taking linezolid. Quantities of tyramine consumed should be less than 100 mg per meal. Foods high in tyramine content include those that may have undergone protein changes by aging, fermentation, pickling, or smoking to improve flavor, such as aged cheeses (0 to 15 mg tyramine per ounce); fermented or air-dried meats (0.1 to 8 mg tyramine per ounce); sauerkraut (8 mg tyramine per 8 ounces); soy sauce (5 mg tyramine per 1 teaspoon); tap beers (4 mg tyramine per 12 ounces); red wines (0 to 6 mg tyramine per 8 ounces). The tyramine content of any protein-rich food may be increased if stored for long periods or improperly refrigerated.9
- They should inform their physician if taking medications containing pseudoephedrine HCl or phenylpropanolamine HCl, such as cold remedies and decongestants.
- They should inform their physician if taking serotonin re-uptake inhibitors or other antidepressants.
- They should inform their physician if they experience changes in vision.
- They should inform their physician if they have a history of seizures.
- Diarrhea is a common problem caused by antibiotics, which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, patients should contact their physician as soon as possible.

10. DETAILS OF MANUFACTURER
Refer Pack for manufacturer details.

Marketed By :
Abbott Healthcare Pvt. Ltd.
Angel Space, Bldg. D-4, Gala No. 1 to 3 &
11 to 13 Ground Floor, 101 to 106 &
111 to 116 First Floor, 201 to 206 & 211 to 216
2nd Floor, Pimplas, Dist. Thane, Bhiwandi - 421 302,
Maharashtra, India.

11. DETAILS OF PERMISSION OR LICENCE NUMBER
Refer Pack for Permission/License details.

12. DATE OF REVISION
Version 6.0 Dated 25-Jun-26

For Product Complaints/Adverse events or Queries please write to
webmasterindia@abbott.com

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Version 6.0 Dated 25-Jun-26
Replaces Version 5.0 Dated 28-Nov-2025