Factim®

(Gemifloxacin) 320mg Tablets

COMPOSITION
Each film-coated **Factim®** tablet contains gemifloxacin mesylate equivalent to 320 mg gemifloxacin.

DESCRIPTION
Factim® (gemifloxacin) is a synthetic broad-spectrum antibacterial agent for oral administration. Gemifloxacin, a compound related to the fluoroquinolone class of antibiotics, is available as the mesylate salt in the sesquihydrate form. Chemically, gemifloxacin is (R,S)-7-[(4Z)-3-(aminomethyl)-4-(methoxyimino)-1-pyrrolidinyl]-1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-1,8-naphthyridine-3-carboxylic acid.

CLINICAL PHARMACOLOGY
Pharmacokinetics
The pharmacokinetics of gemifloxacin are approximately linear over the dose range from 40 mg to 640 mg. There was minimal accumulation of gemifloxacin following multiple oral doses up to 640 mg a day for 7 days (mean accumulation <20%). Following repeat oral administration of 320 mg gemifloxacin once daily, steady-state is achieved by the third day of dosing.

Absorption and Bioavailability
Gemifloxacin, given as an oral tablet, is rapidly absorbed from the gastrointestinal tract. Peak plasma concentrations of gemifloxacin were observed between 0.5 and 2 hours following oral tablet administration and the absolute bioavailability of the 320 mg tablet averaged approximately 71% (95% CI 60%-84%). Following repeat oral doses of 320 mg to healthy subjects, the mean ± SD maximal gemifloxacin plasma concentrations (C_{max}) and systemic drug exposure (AUC (0 - 24)) were 1.61 ± 0.51 µg/mL (range 0.70 - 2.62 µg/mL) and 9.93 ± 3.07 µghr/mL (range 4.71 - 20.1 µghr/mL), respectively. In patients with respiratory and urinary tract infections (n= 1423), similar estimates of systemic drug exposure were determined using a population pharmacokinetics analysis (geometric mean AUC (0 - 24), 8.36 µghr/mL; range 3.2 - 47.7 µghr/mL. The pharmacokinetics of gemifloxacin were not significantly altered when a 320 mg dose was administered with a high-fat meal. Therefore **Factim®** tablets may be administered without regard to meals.

Distribution
In vitro binding of gemifloxacin to plasma proteins in healthy subjects is approximately 60 to 70% and is concentration independent. After repeated doses, the in vivo plasma protein binding in healthy elderly and young subjects ranged from 55% to 73% and was unaffected by age. Renal impairment does not significantly affect the protein binding of gemifloxacin. The blood-to-plasma concentration ratio of gemifloxacin was 1.2:1. The geometric mean for Vdss/F is 4.18 L/kg (range, 1.66 -12.12L/kg). Gemifloxacin is widely distributed throughout the body after oral administration. Concentrations of gemifloxacin in bronchoalveolar lavage fluid exceed those in the plasma. Gemifloxacin penetrates well into lung tissue and fluids. After five daily doses of 320 mg gemifloxacin concentrations in plasma, bronchoalveolar macrophages, epithelial lining fluid and bronchial mucosa at approximately 2 hours were as in Table:

Gemifloxacin Concentrations in Plasma and Tissues (320 mg Oral Dosing)

Tissue	Concentration (mean ±SD)	Ratio compared with plasma (mean ±SD)
Plasma	1. 40 (0.442)µg/mL	—
Bronchoalveolar Macrophages	107(77)µg/g	90.5(106.3)
Epithelial Lining Fluid	2.69 (1.96)µg/mL	1.99(1.32)
Bronchial Mucosa	9.52 (5.15) µg/g	7.21 (4.03)

Metabolism
Gemifloxacin is metabolized to a limited extent by the liver. The unchanged compound is the predominant drug-related component detected in plasma (approximately 65%) upto 4 hours after dosing. All metabolites formed are minor (<10% of the administered oral dose); the principal ones are N-acetyl gemifloxacin, the E-isomer of gemifloxacin and the carbamyl glucuronide of gemifloxacin. Cytochrome P450 enzymes do not play an important role in gemifloxacin metabolism, and the metabolic activity of these enzymes is not significantly inhibited by gemifloxacin.

Excretion
Gemifloxacin and its metabolites are excreted via dual routes of excretion. Following oral administration of gemifloxacin to healthy subjects, a mean (± SD) of 61 ±9.5% of the dose was excreted in the feces and 36 ±9.3% in the urine as unchanged drug and metabolites. The mean (± SD) renal clearance following repeat doses of 320 mg was approximately 11.6 ± 3.9 L/hr (range 4.6-17.6 L/hr), which indicates active secretion is involved in the renal excretion of gemifloxacin. The mean (± SD) plasma elimination half-life at steady state following 320 mg to healthy subjects was approximately 7 ± 2 hours (range 4-12 hours).

Special Populations
Pediatric: The pharmacokinetics of gemifloxacin in pediatric subjects have not been studied.
Geriatric: In adult subjects the pharmacokinetics of gemifloxacin are not affected by age.
Gender: No gemifloxacin dosage adjustment based on gender is necessary.

Hepatic Insufficiency: The pharmacokinetics following a single 320 mg dose of gemifloxacin were studied in patients with mild(Child-Pugh Class A) to moderate (Child- Pugh Class B) liver disease. There was a mean increase in AUC (0-inf) of 34% and a mean increase in Cmax of 25% in these patients with hepatic impairment compared to healthy volunteers. The pharmacokinetics of a single 320 mg dose of gemifloxacin were also studied in patients with severe hepatic impairment (Child-Pugh Class C). There was a mean increase in AUC (0-inf) of 45% and a mean increase in C_{max} of 41% in these subjects with hepatic impairment compared to healthy volunteers. These average pharmacokinetic increases are not considered to be clinically significant. There was no significant change in plasma elimination half-life in the mild, moderate or severe hepatic impairment patients. No dosage adjustment is recommended in patients with mild (Child-Pugh Class A), moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment.

Renal Insufficiency: Results from population pharmacokinetic and clinical pharmacology studies with repeated 320 mg doses indicate the clearance of gemifloxacin is reduced and the plasma elimination is prolonged, leading to an average increase in AUC values of approximately 70% in patients with renal insufficiency. In the pharmacokinetic studies, gemifloxacin C_{max} was not significantly altered in subjects with renal insufficiency. Dose adjustment in patients with creatinine clearance >40 mL/min is not required. Modification of the dosage is recommended for patients with creatinine clearance ≤ 40mL/min. Hemodialysis removes approximately 20 to 30% of an oral dose of gemifloxacin from plasma.

Photosensitivity Potential: In a study of the skin response to ultraviolet and visible radiation conducted in 40 healthy volunteers, the minimum erythematous dose (MED) was assessed following administration of either gemifloxacin 160 mg once daily, gemifloxacin 320 mg once daily, ciprofloxacin 500 mg BID, or placebo for 7 days. At 5 of the 6 wavelengths tested (295-430 nm), the photosensitvity potential of gemifloxacin was not statistically different from placebo. At 365 nm (UVA region), gemifloxacin showed a photosensitivity potential similar to that of ciprofloxacin 500 mg BID and the photosensitivity potential for both drugs were statistically greater than that of placebo. Photosensitivity reactions were reported rarely in clinical trials with gemifloxacin (0.039%).

Drug Interactions:
Antacids/Di- and Trivalent Cations: The systemic availability of gemifloxacin is significantly reduced when an aluminum- and magnesium- containing antacid is concomitantly administered (AUC decreased 85%; Cmax decreased 87%). Administration of an aluminum- and magnesium- containing antacid or ferrous sulfate (325 mg) at 3 hours before or at 2 hours after gemifloxacin did not significantly alter the systemic availability of gemifloxacin. Therefore, aluminum- and / or magnesium- containing antacids, ferrous sulfate (iron), multivitamin preparations containing zinc or other metal cations, or didanosine chewable/buffered tablets or the pediatric powder for oral solution should not be taken within 3 hours before or 2 hours after taking **Factim®** tablets. Calcium carbonate (1000 mg) given either 2 hr before or 2 hr after gemifloxacin administration showed no notable reduction in gemifloxacin systemic availability. Calcium carbonate administered simultaneously with gemifloxacin resulted in a small, not clinically significant, decrease in gemifloxacin exposure [AUC (0-inf) decreased 21 % and C_{max} decreased].
Sucralfate: When sucralfate (2 g) was administered 3 hours prior to gemifloxacin, the oral bio-availability of gemifloxacin was significantly reduced (53% decrease in AUC; 69% decrease in C_{max}). When sucralfate (2 g) was administered 2 hours after gemifloxacin, the oral bioavailabillty of gemifloxacin was not significantly affected; therefore **Factim®** should not be taken at least 2 hours before sucralfate. **In Vitro Metabolism:** Results of in vitro inhibition studies indicate that hepatic cytochrome P450 (CYP450) enzymes do not play an important role in gemifloxacin metabolism. Therefore gemifloxacin should not cause significant in vivo pharmacokinetic interactions with other drugs that are metabolized by CYP450 enzymes.
Theophylline: Gemifloxacin 320 mg at steady-state did not affect the repeat dose pharmacokinetics of theophylline (300 to 400 mg BID to healthy male subjects).
Digoxin: Gemifloxacin 320 mg at steady-state did not affect the repeat dose pharmacokinetics of digoxin (0.25 mg once daily to healthy elderly subjects).
Oral Contraceptives: The effect of an oral estrogen/progesterone contraceptive product (once daily for 21 days) on the pharmacokinetics of gemifloxacin (320 mg once daily for 6 days) in healthy female subjects indicates that concomitant administration caused an average reduction in gemifloxacin AUC and C_{max} of 19% and 12%. These changes are not considered clinically significant. Gemifloxacin 320 mg at steady-state did not affect the repeat dose pharmacokinetics of an ethinylestradiol / levonorgestrol oral contraceptive product (30 µg/150 µg once daily for 21 days to healthy female subjects).
Cimetidine: Co-administration of a single dose of 320 mg gemifloxacin with cimetidine 400 mg four times daily for 7 days resulted in slight average increases in gemifloxacin AUC (0-inf) and C_{max} of 10% and 6%, respectively. These increases are not considered clinically significant.
Omeprazole: Co-administration of a single dose of 320 mg gemifloxacin with omeprazole 40 mg once daily for 4 days resulted in slight average increases in gemifloxacin AUC (0-inf) and C_{max} of 10% and 11%, respectively. These increases are not considered clinically significant.
Warfarin: Administration of repeated doses of gemifloxacin (320 mg once daily for 7 days) to healthy subjects on stable Warfarin therapy had no significant effect on warfarin-induced anticoagulant activity (i.e., International Normalized Ratios for prothrombin Time).
Probenecid: Administration of a single dose of 320 mg gemifloxacin to healthy subjects who also received repeat doses of probenecid (total dose = 4.5 g) reduced the mean renal clearance of gemifloxacin by approximately 50%, resulting in a mean increase of 45% in gemifloxacin AUC (0-inf) and a prolongation of mean half-life by 1.6 hours. Mean gemifloxacin C_{max} increased 8%.

Microbiology
Gemifloxacin has in vitro activity against a wide range of Gram-negative and Gram-positive microorganisms. Gemifloxacin is bictericidal with minimum bactericidal concentrations (MBCs) generally within one dilution of the minimum inhibitory concentrations (MICs). Gemifloxacin acts by inhibiting DNA synthesis through the inhibition of both DNA gyrase and topoisomerase IV (TOPO IV), which are essential for bacterial growth. Streptococcus pneumoniae showing mutations in both DNA gyrase and TOPO IV (double mutants) are resistant to most fluoroquinolones. Gemifloxacin has the ability to inhibit both enzyme systems at therapeutically relevant drug levels in S. pneumoniae(dual targeting), and has MIC values that are still in the susceptible range for some of these double mutants. The mechanism of action of quinolones, including gemifloxacin, is different from that of macrolides, beta-lactams, aminoglycosides, or tetracyclines; therefore, microorganisms resistant to these classes of drugs may be susceptible to gemifloxacin and other quinolones. There is no known cross-resistance between gemifloxacin and the above mentioned classes of antimicrobials. The main mechanism of fluoroquinolone resistance is due to mutations in DNA gyrase and/or TOPO IV. Resistance to gemifloxacin develops slowly via multistep mutations and efflux in a manner similar to other fluoroquinolones. The frequency of spontaneous mutation is low (10-7 to <10-10). Although cross-resistance has been observed between gemifloxacin and other fluoroquinolones, some microorganisms resistant to other fluoroquinolones may be susceptible to gemifloxacin.

Aerobic Gram-Positive Microorganisms: Streptococcus pneumoniae (including multi-drug resistant strains [MDRSP] * *MDRSP: multi-drug resistant Streptococcus pneumoniae, includes isolates previously known as PRSP (penicillin-resistant Streptococcus pneumoniae), and are strains resistant to two or more of the following antibiotics: penicillin, 2nd generation cephalosporins (e.g., cefuroxime), macrolides, tetracyclines and trimethoprim/sulfamethoxazole.
Aerobic Gram-Negative Microorganisms: Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae(many strains are only moderately susceptible), Moraxella catarrhalis.
Other Microorganisms: Chlamydia pneumoniae, Mycoplasma pneumoniae, The following data are available, but their clinical significance is unknown.
Gemifloxacin exhibits in vitro minimal inhibitory concentrations (MICs) of 0.25 µg/mL or less against most (≥90%) strains of the following microorganisms; however, the safety and effectiveness of gemifloxacin in treating clinical infections due to these microorganisms has not been established in adequate and well controlled clinical trials:
Aerobic Gram-Positive Microorganisms : Staphylococcus aureus(methicillin-susceptible strains only), Streptococcus pyogenes **Aerobic Gram-Negative Microorganisms:** Acinetobacter Iwoffii, Klebsiella oxytoca, Legionella pneumophila, Proteus vulgaris

INDICATIONS AND USAGE
Factim® is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the conditions listed below.

Acute bacterial exacerbation of chronic bronchitis caused by Streptococcus pneumoniae, Haemophilus influenzae, Haemophilus parainfluenzae, or Moraxella catarrhalis.
Community-acquired pneumonia (of mild to moderate severity) caused by Streptococcus pneumoniae (including multi-drug resistant strains [MDRSP]*, Haemophilus influenzae, Moraxella catarrhalis, Mycoplasma pneumoniae. Chlamydia pneumoniae, or Klebsiella pneumoniae.
*MDRSP, multi-drug resistant Streptococcus pneumoniae, includes isolates previously known as PRSP (penicillin-resistant Streptococcus pneumoniae), and are strains resistant to two or more of the following antibiotics: penicillin. 2nd generation cephalosporins (e.g, cefuroxime). macrolides, tetracyclines and trimethoprim/sulfamethoxazole.

CONTRAINDICATIONS:
Factim® is contraindicated in patients with a history of hypersensitivity to gemifloxacin, fluoroquinolone antibiotic agents, or any of the product components.

WARNINGS:
THE SAFETY AND EFFECTIVENESS OF **FACTIM®** IN CHILDREN. ADOLESCENTS (LESS THAN 18 YEARS OF AGE), PREGNANT WOMEN AND LACTATING WOMEN HAVE NOT BEEN ESTABLISHED.

QT Effects: Fluoroquinolones may prolong the QT interval in some patients. Gemifloxacin should be avoided in patients with a history of prolongation of the QTc interval, patients with uncorrected electrolyte disorders (hypokalemia or hypomagnesemia), and in patients receiving Class IA (e.g., quinidine, procainamide) or Class III (e.g., amiodarone, sotalol) antiarrhythmic agents.
The likelihood of QTc prolongation may increase with increasing dose of the drug; therefore, the recommended dose should not be exceeded especially in patients with renal or hepatic impairment where the C_{max} and AUC are slightly higher. Qtc prolongation may lead to an increased risk for ventricular arrhythmias including torsades de pointes. The maximal change in the QTc interval occurs approximately 5-10 hours following oral administration of gemifloxacin.

Hypersensitivity Reactions: Serious hypersensitivity and/or anaphylactic reactions have been reported in patients receiving fluoroquinolone therapy including **Factim®**. Some reactions have been accompanied by cardiovascular collapse, hypotension/shock, seizure, loss of consciousness, tingling, angioedema (including tongue, laryngeal, throat or facial edema/swelling), airway obstruction (including bronchospasm, shortness of breath and acute respiratory distress), dyspnea, urticaria, itching and other serious skin reactions.

Peripheral Neuropathy: Rare cases of sensory or sensory motor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias. hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones.

Tendon Effects: Factim® should be discontinued if the patient experiences pain, inflammation, or rupture of a tendon. Patients should rest and refrain from exercise until the diagnosis of tendonitis or tendon rupture has been excluded. Tendon rupture can occur during or after therapy with quinolones.

CNS Effects: As with other fluoroquinolones, **Factim®** should be used with caution in patients with CNS diseases such as epilepsy or patients predisposed to convulsions. Although not seen in **Factim®** clinical trials, convulsions, increased intracranial pressure, and toxic psychosis have been reported in patients receiving other fluoroquinolones. CNS stimulation which may lead to tremors, restlessness, anxiety, lightheadedness, confusion, hallucinations, paranoia, depression, insomnia, and rarely suicidal thoughts or acts may also be caused by other fluoroquinolones. If these reactions occur in patients receiving **Factim®**, the drug should be discontinued and appropriate measures instituted.

Clostridium Difficile Associated Diarrhea: Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including **Factim®** and may range in severity from mild to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of C. difficile.

PRECAUTIONS
General: Prescribing **Factim®** in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Rash: The most common form of rash associated with **Factim®** was described as maculopapular and mild to moderate in severity. Eighty percent of rashes resolved within 14 days. Approximately 10% of the rashes (0.5% all patients) were described as of severe intensity and approximately 10% of those with rash were treated with systemic steroids. **Factim®** should be discontinued in patients developing a rash or urticaria while on treatment.
Photosensitivity reactions have been reported very rarely in clinical trials with **Factim®**. However, as with all drugs of this class, it is recommended that patients avoid unnecessary exposure to strong sunlight or artificial UV rays (e.g., sunlamps, solariums), and should be advised of the appropriate use of broad spectrum sun block if in bright sunlight. Treatment should be discontinued if a photosensitivity reaction is suspected.

Hepatic Effects: Liver enzyme elevations (increased ALT and/or AST) occurred at similar rates in patients receiving **Factim®** 320 mg daily relative to comparator antimicrobial agents (ciprofloxacin, levofloxacin, clarithromycin/cefuroxime axetil, amoxicillin/ clavulanate potassium, and ofloxacin). In patients who received **Factim®** at doses of 480 mg per day or greater there was an increased incidence of elevations in liver enzymes. There were no clinical symptoms associated with these liver enzyme elevations. The liver enzyme elevations resolved following cessation of therapy.

Renal Effects: Alteration of the dosage regimen is necessary for patients with impairment of renal function (creatinine clearance ≤ 40 mL/min). Adequate hydration of patients receiving **Factim®** should be maintained to prevent the formation of a highly concentrated urine.

Pregnancy: There are no adequate and well-controlled studies in pregnant women. The safety of gemifloxacin in pregnant women has not been established. Gemifloxacin should not be used in pregnant women unless the potential benefit to the mother outweighs the risk to the fetus.
Nursing Mothers: There is no information on excretion of gemifloxacin into human milk. Therefore, gemifloxacin should not be used in lactating women unless the potential benefit to the mother outweighs the risk.
Pediatric Use: Safety and effectiveness in children and adolescents less than 18 years of age have not been established.

ADVERSE REACTIONS
The most commonly reported adverse events with a frequency of ≥ 2% for patients who received 320 mg of gemifloxacin were as follows; rash, nausea, diarrhea, vomiting. and headache.
adverse events with a frequency of ≥ 0.1% to 1% were: abdominal pain, anorexia, constipation, dermatitis, dizziness, dry mouth, dyspepsia, fatigue, flatulence, fungal infection, gastritis, genital moniliasis, genital pruritis, hyperglycemia, increased alkaline phosphatase, increased ALT, increased AST, increased creatine phosphokinase, insomnia, leukopenia, pruritus, somnolence, taste perversion, thrombocythemia, urticaria and vaginitis.

Adverse events with a frequency of ≤ 0.1 % of patients were: abnormal urine, vision abnormality, anemia, arthralgia, asthenia, back pain, bilirubinemia, dyspnea, eczema, eosinophilia, facial edema, flushing, gastroenteritis, granulocytopenia, hot flashes, increased GGT, increased non-protein nitrogen, leg cramps, moniliasis, myalgia, nervousness, non-specified gastrointestinal disorder, pain, pharyngitis, pneumonia, thrombocytopenia, tremor and vertigo.

OVERDOSAGE
Any signs or symptoms of overdosage should be treated symptomatically. No specific antidote is known. In the event of acute oral overdosage, the stomach should be emptied by inducing vomiting or by gastric lavage; the patient should be carefully observed and treated symptomatically with appropriate hydration maintained. Hemodialysis removes approximately 20 to 30% of an oral dose of gemifloxacin from plasma.

DOSAGE AND ADMINISTRATION
Factim® can be taken with or without food and should be swallowed whole with a liberal amount of liquid. The recommended dose of **Factim®** is 320 mg daily, according to the following table.

Recommended Dosage Regimen of Factim®

INDICATIONS	DOSE / DURATION
Acute bacterial exacerbation of chronic bronchitis	One 320 mg tablet daily for 5 days
Community-acquired pneumonia (of mild to moderate severity)	
due to known or suspected S. pneumoniae, H. influenzae, M. pneumoniae, or C. pneumoniae infection	One 320 mg tablet daily for 5 days
due to known or suspected MDRSP*, K. pneumoniae, or catarrhalis infection	One 320 mg tablet daily for 7 days

*MDRSP: multi-drug resistant Streptococcus pneumoniae, includes isolates previously known as PRSP (penicillin-resistant Streptococcus pneumoniae), and are strains resistant to two or more of the following antibiotics: penicillin, 2nd generation cephalosporins (e.g., cefuroxime), macrolides, tetracyclines and trimethoprim/sulfamethoxazole.
The recommended dose and duration of **Factim®** should not be exceeded.

Use in Renally Impaired Patients: Dose adjustment in patients with creatinine clearance ≥ 40 mL/min is not required. Modification of the dosage is recommended for patients with creatinine clearance ≤ 40 mL/min.

Recommended Dose for Patients with Renal Impairment

Creatinine Clearance (mL/min)	Dose
> 40	See Usual Dosage
≤ 40	160 mg every 24 hours

Use in Hepatically Impaired Patients: No dosage adjustment is recommended in patients with mild (Child-Pugh Class A), moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment.

STORAGE: Store below 30°C in a dry place.
Protect from heat and light.
The expiry date refers to the product correctly stored at the required conditions.

HOW SUPPLIED: **Factim®** is available in 1x7's Alu-Alu blister pack
Keep out of reach of children.

فیکٹم گولیاں

(جیمی فلاکساسن) ۳۲۰ ملی گرام

اجزائے ترکیبی اور وضاحت:

فیکٹم میں جیمی فلاکساسن ۳۲۰ ملی گرام بطور عامل جز شامل ہے۔

علامات:

فیکٹم شدید انفیکشن کی علامات کے علاج میں مئوثر ہے۔ جیسے شدید اور پرانی برونکائی کی سوزش اور کمیونٹی ایکوائرڈ نمونیہ۔

خوراک:

فیکٹم ایک گولی روزانہ، مکمل گولی زیادہ پانی کے ساتھ نگل لیں۔

ممانعت برائے علاج:

دوا میں موجود کسی جز سے اور فلوروکیونولون اینٹی بائیوٹکس سے ذودحسی (Hypersensitivity) ہو۔ حاملہ اور دودھ پلانے والی خواتین میں ممانعت ہے۔

بچوں میں اس کے محفوظ ہونے اور افادیت کے بارے میں شواہد/معلومات نہیں۔

منفی اور مضر اثرات:

بے چینی، کپکپی، چکر آنا، الرجی، ہائپوگلائی سیمیا۔

پیکنگ:

فیکٹم کا ایک پیک ۷ گولیوں پر مشتمل ہے۔

خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

صرف مستند ڈاکٹر کے نسخہ پر ہی فروخت کریں۔

تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

دوا کو 30°C سے کم درجہ حرارت پر نمی اور روشنی سے محفوظ رکھیں۔

Manufactured by:
Hansel Pharmaceuticals (Pvt) Ltd.
Plot No. 2, Pharma City, 30 Km Multan Road,
Sundar, Lahore - Pakistan.

Marketed by:
CHIESI PHARMACEUTICALS (PVT) LTD.
60/1A - XX, Phase III, Commercial Zone, Khayaban-e-Iqbal, D.H.A. Lahore-5400 Pakistan

Chiesi