1.0 Name of the Finished Pharmaceutical Product

Ceftriaxone & Tazobactum For Injection

1.1 Strength

1125 mg

1.2 Pharmaceutical Dosage Form

IM & IV only

2.0 Qualitative And Quantitative Composition

2.1 Qualitative Declaration

The injection contain Ceftriaxone Sodium & Tazobactum Sodium.

2.2 Quantitative Declaration

Each vial contains:

Sterile Ceftriaxone Sodium BP

Eq to Ceftriaxone 1000mg

Sterile Tazobactum Sodium BP

Eq to Tazobactum 125mg

3.0 Pharmaceutical Form

Dry Powder Injection

White crystalline powder filled and sealed in transparent glass vial.

4.0 Clinical Particulars

4.1 Therapeutic Indications

The combination of tazobactam and ceftriaxone is active against all the organisms sensitive to ceftriaxone. In addition, it demonstrates synergistic activity (reduction in minimal inhibitory concentrations [MICs] for the combination versus those of each component) in a variety of organisms.

It is mainly indicated in the following conditions:

• Lower respiratory tract infections and community-acquired pneumonia

• Acute bacterial otitis media

• Skin and skin structure infections
• Urinary tract infections
• Uncomplicated gonorrhea
• Pelvic inflammatory disease
• Bacterial septicemia
• Bone and joint infections
• Intra-abdominal infections
• Bacterial meningitis
• Peri-operative prophylaxis of infections associated with surgery

4.2 Posology and Method of Administration

Ceftriaxone & Tazobactum For Injection may be administered by the I.V. or I.M. Route.

Dosage and mode of administration should be determined by the severity of the infection, susceptibility of the causative organism and the patient's condition. Under most circumstances a once-daily dose — or, in the specified indications, a single dose — will give satisfactory therapeutic results.

Note: The dosage recommendations are in terms of ceftriaxone alone.

Adults and Children Aged 12 Years and Over

The usual adult dose is 1 g given once a day (or in equally divided doses twice a day), depending upon the severity of the infection.

For severe infections, 2–4 g daily, normally as a single dose every 24 hours.

For infections caused by *Staphylococcus aureus* (methicillin-susceptible *S. Aureus*), the recommended daily dose is 2–4 g, in order to achieve >90% target attainment.The total daily dose should not exceed 4 g.

If *Chlamydia trachomatis* is a suspected pathogen, appropriate anti-chlamydial coverage should be added, because ceftriaxone sodium has no activity against this organism.

For the treatment of uncomplicated gonococcal infections, a single I.M. dose of 250 mg is recommended.

Simultaneous administration of probenecid is not indicated.

For pre-operative use (surgical prophylaxis), a single I.V. dose of 1 g administered half-hour to 2 hours before surgery is recommended. In colorectal surgery, a 2 g I.M. dose should be given (dosages greater than 1 g should be divided and injected at more than one site), or by slow I.V. infusion, in conjunction with a suitable agent against anaerobic bacteria.

Generally, ceftriaxone/tazobactam should be continued for at least 2 days after the signs and symptoms of infection have disappeared. The usual duration of therapy is 4–14 days; in complicated infections, longer therapy may be required. When treating *Streptococci pyogenes*, the therapy should be continued for at least 10 days.

Elderly Patients

These dosages do not require modification in elderly patients provided that renal and hepatic functions are satisfactory.

Paediatric Patients

Neonates

A daily dose of 20–50 mg/kg body weight, not to exceed 50 mg/kg.

In the neonate, the I.V. dose should be given over 60 minutes to reduce the displacement of bilirubin from albumin, thereby reducing the potential risk of bilirubin encephalopathy.

Infants and Children Aged up to 12 Years

Standard therapeutic dosage: 20–50 mg/kg body weight once daily.

For the treatment of skin and skin structure infections, the recommended total daily dose is 50 to 75 mg/kg given once a day (or in equally divided doses twice a day). The total daily dose should not exceed 2 g.

For the treatment of acute bacterial otitis media, a single I.M. dose of 50 mg/kg (not to exceed 1 g) is recommended.

For the treatment of serious miscellaneous infections other than meningitis, the recommended total daily dose is 50–75 mg/kg, given in divided doses every 12 hours. The total daily dose should not exceed 2 g.

In the treatment of meningitis, it is recommended that the initial therapeutic dose be 100 mg/kg (not to exceed 4 g). Thereafter, a total daily dose of 100 mg/kg/day (not to exceed 4 g daily) is recommended. The daily dose may be administered once a day (or in equally divided doses every 12 hours). The usual duration of therapy is 7–14 days.

In severe infections, up to 80 mg/kg body weight daily may be given. For children with body weights of 50 kg or more, the usual adult dosage should be used. Doses of 50 mg/kg or over should be given by slow I.V. infusion over at least 30 minutes. Doses greater than 80 mg/kg body weight should be avoided because of the increased risk of biliary precipitates.

Renal and Hepatic Impairment

In patients with impaired renal function, there is no need to reduce the dosage of Ceftriaxone & Tazobactum For Injection provided liver function is intact. Only in cases of pre-terminal renal failure (creatinine clearance <10 ml per minute) should the daily dosage be limited to 2 g or less.

In patients with liver damage there is no need for the dosage to be reduced provided renal function is intact.

In severe renal impairment accompanied by hepatic insufficiency, the plasma concentration of Ceftriaxone & Tazobactum For Injection should be determined at regular intervals and dosage adjusted.

In patients undergoing dialysis, no additional supplementary dosing is required following the dialysis. Serum concentrations should be monitored, however, to determine whether dosage adjustments are necessary, since the elimination rate in these patients may be reduced.

Directions for Use

The use of freshly prepared solutions is recommended.

Ceftriaxone may be administered by deep I.M. injection, or as a slow I.V. injection/infusion, after reconstitution of the solution according to the directions given below:

I.V. injection should be administered over at least 2–4 minutes.

I.V. infusion should be over a period of 30 minutes.

After reconstitution, the solution should be administered by deep *I.M. injection*. Doses greater than 1 g should be divided and injected at more than one site. As with all I.M. preparations, ceftriaxone/tazobactam should be injected well within the body of a relatively large muscle; aspiration helps to avoid unintentional injection into a blood vessel.

Reconstitute ceftriaxone/tazobactam with the appropriate diluent, e.g. Water for Injection, IP, Normal Saline Water, or Dextrose Solutions.

4.3 Contraindications

Ceftriaxone & Tazobactum For Injection is contraindicated in patients with known hypersensitivity to beta-lactam antibiotics. In patients hypersensitive to penicillin, the possibility of allergic cross-reactions should be borne in mind. It is also contraindicated in patients who have had a previous immediate and/or any severe hypersensitivity reaction to any penicillin or to any other beta-lactam drug

Neonates (≤28 days)

Hyperbilirubinaemic neonates, especially prematures, should not be treated with ceftriaxone. *In vitro* studies have shown that ceftriaxone can displace bilirubin from its binding to serum albumin and bilirubin encephalopathy can possibly develop in these patients. Ceftriaxone/tazobactam is contraindicated in premature newborns up to a corrected age of 41 weeks (weeks of gestation + weeks of life).

Ceftriaxone & Tazobactum For Injection is contraindicated in neonates if they require (or are expected to require) treatment with calcium-containing I.V. solutions, including continuous calcium-containing infusions such as parenteral nutrition, because of the risk of precipitation of ceftriaxone calcium.

It is contraindicated in

In some of these cases, the same I.V. infusion line was used for both ceftriaxone and calcium-containing fluids and, in some, a precipitate was observed in the I.V. infusion line. At least one fatality has been reported in a neonate in whom ceftriaxone and calcium-containing fluids were administered at different time points via different I.V. lines; no crystalline material was observed at autopsy in this neonate. There have been no similar reports in patients other than neonates.

4.4 Special Warning And Precautions For Use

Before therapy with ceftriaxone/tazobactam is instituted, a detailed inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cephalosporins, penicillins or other drugs. This product should be given cautiously to penicillin-sensitive patients. Serious acute hypersensitivity reactions may require the use of subcutaneous epinephrine and other emergency measures.

Ceftriaxone should be given with caution to patients who have other allergic diatheses.

Do not use diluents containing calcium, such as Ringers solution or Hartmann’s solution, to reconstitute ceftriaxone/tazobactam injection vials or to further dilute a reconstituted vial for I.V. administration because a precipitate can form. Precipitation of ceftriaxone calcium can also occur when ceftriaxone/tazobactam injection is mixed with calcium-containing solutions in the same I.V. administration line. Ceftriaxone/tazobactam injection must not be administered simultaneously with calcium-containing I.V. solutions, including continuous calcium-containing infusions such as parenteral nutrition via a Y-site. However, in patients other than neonates, ceftriaxone/tazobactam injection and calcium-containing solutions may be

administered sequentially of one another if the infusion lines are thoroughly flushed between infusions with a compatible fluid. *In vitro* studies using adult and neonatal plasma from umbilical cord blood demonstrated that neonates have an increased risk of precipitation of ceftriaxone calcium.

Clostridium difficile-associated diarrhoea (CDAD) has been reported with nearly all antibacterial agents, including ceftriaxone/tazobactam, and may range in severity from mild to life-threatening. Treatment with antibacterial agents alters the normal flora of the colon, leading to overgrowth of *C. difficile*. Therefore, it is important to consider this diagnosis in patients who present with diarrhoea subsequent to the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

Superinfections with non-susceptible microorganisms may occur as with other antibacterial agents.

Antibiotic-associated diarrhoea, colitis and pseudomembranous colitis have all been reported with the use of ceftriaxone. These diagnoses should be considered in any patient who develops diarrhoea during or shortly after treatment. Ceftriaxone should be discontinued if severe and/or bloody diarrhoea occurs during treatment and appropriate therapy instituted.

As with other cephalosporins, prolonged use of ceftriaxone may result in the overgrowth of non-susceptible organisms, such as *Enterococci* and *Candida* spp.

An immune-mediated haemolytic anaemia has been observed in patients receiving cephalosporin class-antibacterials, including ceftriaxone/tazobactam. Severe cases of haemolytic anaemia, including fatalities, have been reported during treatment in both adults and children. If a patient develops anaemia while on ceftriaxone, the diagnosis of a cephalosporin-associated anaemia should be considered and ceftriaxone stopped until the aetiology is determined.

Although transient elevations of BUN and serum creatinine have been observed, at the recommended dosages, the nephrotoxic potential of ceftriaxone/tazobactam is similar to that of other cephalosporins.

Alterations in prothrombin times have occurred infrequently in patients treated with ceftriaxone/tazobactam. Patients with impaired vitamin K synthesis or low vitamin K stores (e.g. chronic hepatic disease and malnutrition) may require monitoring of prothrombin time

during ceftriaxone/tazobactam injection treatment. Vitamin K administration (10 mg weekly) may be necessary if the prothrombin time is prolonged before or during therapy.

Prolonged use of ceftriaxone/tazobactam may result in the overgrowth of non-susceptible organisms. Hence, careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Ceftriaxone/tazobactam injection should be prescribed with caution in individuals with a history of gastrointestinal disease, especially colitis. There have been reports of sonographic abnormalities in the gall bladder of patients treated with ceftriaxone/tazobactam; some of these patients also had symptoms of gall bladder disease. On a sonography, these abnormalities appear as an echo without acoustical shadowing, suggesting sludge, or as an echo with acoustical shadowing, which may be misinterpreted as gallstones. The chemical nature of the sonographically-detected material has been determined to be, predominantly, a ceftriaxone calcium salt. The condition appears to be transient and reversible upon the discontinuation of ceftriaxone/tazobactam and the institution of conservative non-surgical management. Therefore, ceftriaxone/tazobactam should be discontinued in patients who develop signs and symptoms suggestive of gall bladder disease and/or the sonographic findings described above.

Cases of pancreatitis, possibly secondary to biliary obstruction, have been reported rarely in patients treated with ceftriaxone/tazobactam. Most patients presented with risk factors for biliary stasis and biliary sludge (preceding major therapy, severe illness, total parenteral nutrition). A trigger/co-factor role of ceftriaxone/tazobactam-related biliary precipitation cannot be ruled out. As with other cephalosporins, anaphylactic shock/fatal outcomes cannot be ruled out even if a thorough patient history is taken and even if the patient is not known to be allergic or previously exposed.

Prescribing ceftriaxone/tazobactam injection in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Ceftriaxone/tazobactam may precipitate in the gallbladder and then be detectable as shadows on ultrasound. This can happen in patients of any age, but is more likely in infants and small children who are usually given a larger dose of ceftriaxone/tazobactam on a body weight basis. In children, doses greater than 80 mg/kg body weight should be avoided because of the increased risk of biliary precipitates. There is no clear evidence of gallstones or of acute cholecystitis developing in children or infants treated with ceftriaxone/tazobactam. As the condition appears to be transient and reversible upon discontinuation, therapeutic procedures are not normally indicated.

Studies have shown that ceftriaxone, like some other cephalosporins, can displace bilirubin from serum albumin. During prolonged treatment, a complete blood count should be performed at regular intervals.

Cephalosporins, as a class, tend to be absorbed onto the surface of the red cell membranes and react with antibodies directed against the drug to produce a positive Coombs' test and, occasionally, a rather mild haemolytic anaemia. In this respect, there may be some cross-reactivity with penicillins.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

Other Antibiotics

No interference with the action or increase in nephrotoxicity of aminoglycosides has been observed during simultaneous administration with ceftriaxone/tazobactam.

In an *in vitro* study, antagonistic effects have been observed with the combination of chloramphenicol and ceftriaxone. The clinical relevance of this finding is unknown, but caution is advised if concurrent administration of ceftriaxone with chloramphenicol is proposed.

Diuretics

No impairment of renal function has so far been observed after concurrent administration of large doses of ceftriaxone/tazobactam and potent diuretics (e.g. furosemide).

Disulfiram/ Probenecid

No effect similar to that of disulfiram has been demonstrated after ingestion of alcohol subsequent to the administration of ceftriaxone/tazobactam. Ceftriaxone does not contain an N-methylthiotetrazole moiety associated with possible ethanol intolerance and bleeding problems of certain other cephalosporins. The elimination of ceftriaxone/tazobactam is not altered by probenecid.

Contraceptives

Ceftriaxone may adversely affect the efficacy of oral hormonal contraceptives. Consequently, it is advisable to use supplementary (non-hormonal) contraceptive measures during treatment and in the month following treatment.

Renal Impairment

Ceftriaxone is excreted via both biliary and renal excretion. Therefore, patients with renal failure normally require no dosage adjustment when the usual doses of ceftriaxone/tazobactam

injection are administered, but concentrations of the drug in the serum should be monitored periodically. If evidence of accumulation exists, the dosage should be decreased accordingly. No data are available in the case of paediatric patients with impaired renal function.

Hepatic Impairment

Dosage adjustments should not be necessary in patients with hepatic dysfunction; however, in patients with both hepatic dysfunction and significant renal disease, the dosage of ceftriaxone/tazobactam injection should not exceed 2 g daily without close monitoring of serum concentrations. No data are available in the case of paediatric patients with impaired hepatic function.

Pregnancy

For ceftriaxone, limited clinical data on exposed pregnancies are available. Ceftriaxone crosses the placental barrier. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Lactation

Low concentrations of ceftriaxone/tazobactam are excreted in human milk. Hence, caution should be exercised when ceftriaxone/tazobactam is administered to a nursing mother.

Paediatric Use

Safety and effectiveness of ceftriaxone/tazobactam in neonates, infants and paediatric patients have been established for the dosages described in the DOSAGE AND ADMINISTRATION section. *In vitro* studies have shown that ceftriaxone, like some other cephalosporins, can displace bilirubin from serum albumin. Ceftriaxone/tazobactam should not be administered to hyperbilirubinaemic neonates, especially premature.

Geriatric Use

The pharmacokinetics of ceftriaxone/tazobactam were only minimally altered in geriatric patients compared with healthy adult subjects, and dosage adjustments are not necessary for geriatric patients with ceftriaxone/tazobactam dosages up to 2 g per day.

4.6 Fertility, pregnancy and lactation

Pregnancy

ceftriaxone/tazobactam Injection should be used during pregnancy only if clearly needed.

Lactation

Low concentrations of ceftriaxone/tazobactam are excreted in human milk. Hence, caution should be exercised when ceftriaxone/tazobactam is administered to a nursing mother.

4.7 Effects on Ability to Drive and Use Machines

During treatment with ceftriaxone, undesirable effects may occur (e.g. dizziness), which may influence the ability to drive and use machines. Patients should be cautious when driving or operating machinery.

4.8 Undesirable Effects

Ceftriaxone/tazobactam is generally well tolerated.

The most frequently reported adverse events for ceftriaxone are diarrhoea, nausea and vomiting. Other reported adverse events include hypersensitivity reactions such as allergic skin reactions and anaphylactic reactions, secondary infections with yeast, fungi or resistant organisms as well as changes in blood cell counts.

Rarely, severe, and in some cases fatal, adverse reactions have been reported in preterm and full-term newborns (aged <28 days) who had been treated with I.V. ceftriaxone and calcium. Precipitations of ceftriaxone calcium salt have been observed in lung and kidneys post-mortem. The high risk of precipitation in newborns is due to their low blood volume and the longer half-life of ceftriaxone compared with adults.

General Disorders and Administration Site Conditions

Pain, indurations and tenderness was 1% overall.

Rare (≥0.01 – <0.1%): Phlebitis and injection site pain following I.V. administration. This can be minimized by slow injection over at least 2–4 minutes. Rigors, pyrexia.

An I.M. injection *without* lidocaine solution is painful.

Hypersensitivity

Rash (1.7%). Less frequently reported (<1%) were pruritus, fever or chills.

Infections and Infestations

Rare (≥0.01 – <0.1%): Mycosis of the genital tract.

Superinfections of various sites with yeasts, fungi or other resistant organisms are possible.

Blood and Lymphatic System Disorders

Eosinophilia (6%), thrombocytosis (5.1%) and leucopenia (2.1%).

Less frequently reported (<1%) were anaemia, haemolytic anaemia, neutropenia, lymphopenia, thrombocytopenia, and prolongation of the prothrombin time.

Rare (≥0.01 - <0.1%): Agranulocytosis (<500/m^3).

Very rare (<0.01%), including isolated reports: Positive Coombs' test, coagulation disorders, mostly after 10 days of treatment and following total doses of 20 g ceftriaxone and more.

Immune System Disorders

Rare (≥0.01 – <0.1%): Anaphylactic (e.g. bronchospasm) and anaphylactoid reactions.

Nervous System Disorders

Uncommon (<1%): Headache, dizziness.

Gastrointestinal Disorders

Common (≥1 – <10%): Loose stools or diarrhoea, nausea, vomiting.

Uncommon (<1%): Dysgeusia.

Rare (≥0.01 – <0.1%): Stomatitis, glossitis. These side effects are usually mild and commonly disappear during treatment or after discontinuation of treatment.

Very rare (<0.01%), including isolated reports: Pseudomembranous colitis (mostly caused by *Clostridium difficile*), pancreatitis (possibly caused by obstruction of bile ducts). Therefore, the possibility of the disease should be considered in patients who present with diarrhoea following antibacterial agent use.

Hepato-Biliary Disorders

Elevations of SGOT (3.1%) or SGPT (3.3%). Less frequently reported (<1%) were elevations of alkaline phosphatase and bilirubin.

Precipitation of ceftriaxone calcium salt in the gallbladder has been observed, mostly in patients treated with doses higher than the recommended standard dose. In children, prospective studies have shown a variable incidence of precipitation with I.V. application, in some studies to above 30%. The incidence seems to be lower with slow infusion (20–30 minutes). This effect is usually asymptomatic, but, in rare cases, the precipitations have been accompanied by clinical symptoms such as pain, nausea and vomiting. Symptomatic treatment is recommended in these cases. Precipitation is usually reversible upon discontinuation of ceftriaxone.

Skin and Subcutaneous Tissue Disorders

Common (≥1 – <10%): Allergic dermatitis.

Uncommon (≥0.1 – <1%): Allergic skin reactions such as maculopapular rash or exanthema, urticaria, dermatitis, pruritus, oedema.

Very rare (<0.01%), including isolated reports: Erythema multiforme, Stevens Johnson Syndrome, Lyell's Syndrome/toxic epidermal necrolysis.

Renal and Urinary Disorders

Uncommon (<1%): Increase in serum creatinine and the presence of casts in the urine. Moniliasis or vaginitis was reported occasionally.

Rare (≥0.01 – <0.1%): Oliguria, glycosuria, haematuria.

Very rare (<0.01%), including isolated reports: Renal precipitation, mostly in children older than 3 years who had been treated with either high daily doses (80 mg/kg/day and more) or total doses exceeding 10 g and with other risk factors such as dehydration or immobilization. Renal precipitation is reversible upon discontinuation of ceftriaxone. Anuria and renal impairment have been reported in association.

Miscellaneous

Diaphoresis and flushing were reported occasionally (<1%).

Other rarely observed adverse reactions (<0.1%) include abdominal pain, allergic pneumonitis, anaphylaxis, basophilia, biliary lithiasis, colitis, dyspepsia, epistaxis, flatulence, gallbladder sludge, jaundice, leucocytosis, lymphocytosis, monocytosis, nephrolithiasis, palpitations, a decrease in the prothrombin time, seizures, vertigo, and serum sickness.

4.9 Overdose

In the case of overdosage, nausea, vomiting and diarrhoea can occur. The drug concentration would not be reduced by haemodialysis or peritoneal dialysis. There is no specific antidote. Treatment of overdosage should be symptomatic.

5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacodynamics

Ceftriaxone is a 2-aminothiazolyl methoxylmino third-generation cephalosporin derivative. Ceftriaxone, a bactericidal antimicrobial, inhibits bacterial cell wall synthesis of actively dividing cells by binding to one or more penicillin-binding proteins (PBPs). These proteins are associated with the bacterial cell membrane and probably serve in synthesis. The result is the formation of a defective cell wall that is osmotically unstable. Bacterial species have a unique

set of PBPs. The affinity pattern of ceftriaxone for the PBPs for different bacterial species affects the drug's antimicrobial spectrum of activity. It is also felt that cephalosporins, as well as penicillins, may increase the breakdown of the cell wall of the bacteria by decreasing the availability of an inhibitor of murein hydrolase, an enzyme involved in cell division. If unimposed, this enzyme can destroy the integrity of the cell wall.

Tazobactam is a penicillinate sulfone, structurally related to sulbactam. Being a beta-lactamase inhibitor, it is synergistic with many beta-lactamase labile drugs such as penicillins and cephalosporins. Tazobactam inhibits all beta-lactamases inhibited by clavulanic acid, but, in addition, it also has some activity against chromosomally-mediated induced (or derepressed) enzymes of Morganella morganii, Citrobacter freundii, Enterobacter cloacae, Serratia marcescens and Pseudomonas aeruginosa. Tazobactam also appears to be a weaker enzyme inducer than other beta-lactamase inhibitors.

Combination of Tazobactam and Ceftriaxone

The combination of tazobactam and ceftriaxone is active against all the organisms sensitive to ceftriaxone. In addition, it demonstrates synergistic activity (reduction in minimal inhibitory concentrations [MICs] for the combination versus those of each component) in a variety of organisms.

5.2 Pharmacokinetic Properties

Distribution

Ceftriaxone: 98% bound to plasma proteins; crosses the blood brain barrier.

Tazobactam: About 30% bound to plasma proteins; widely distributed to tissues and body fluids.

Excretion

Ceftriaxone: Elimination half-life is about 8.7 hours; 33-67% removed as unchanged drug.
Tazobactam: Removed mainly via kidneys with 80% of an administered dose as unchanged drug

5.3 Preclinical Safety Data

There is evidence from animal studies that high doses of ceftriaxone calcium salt led to formation of concrements and precipitates in the gallbladder of dogs and monkeys, which proved to be reversible. Animal studies produced no evidence of toxicity to reproduction and genotoxicity. Carcinogenicity studies on ceftriaxone were not conducted.

6.0 Pharmaceutical Particulars

6.1 List of Excipients

None

6.2 Incompatibilities

None

6.3 Shelf Life

24 Months

6.4 Special Precautions for Storage

Store protected from light at a temperature between 2^0C to 8^0C.

6.5 Nature and Contents of Container

Combipack of one vial +WFI packed in a carton along with pack insert.

6.6 Instruction for use and Handling

None

7.0 Marketing Authorization Holder and Manufacturing Site Addresses

7.1 Name And Address of Manufacturer

Agron Remedies Pvt Ltd.

Opposite Naveen Anaaj Mandi,

Sarverkhera, Kashipur, Uttarakhand 244713, INDIA

7.2 Name And Address of Principal

NA

8.0 Registration number

Not applicable

9.0 Category for distribution

To be given after approval of product.

10.0 Date of Publication of this Package Insert

Not applicable