SCOTT-EDIL PHARMACIA LTD.

56,EPIP,Phase-I,Jharmajri,Baddi-173 205, (HP), India

Summary of Product Characteristics (SPC)

1. Name of the medicinal product

TYSPART (Sparfloxacin Tablets 200 mg)

1.1 *International Non-Proprietary Name (INN)*

Sparfloxacin

1.2 *Strength*

200 mg

1.3 *Pharmaceutical form*

Tablets for oral administration

2. Qualitative and quantitative composition

Each film coated Tablet contains:

Sparfloxacin	200mg
Excipients	q.s.

Color: Titanium dioxide USP & Quinoline Yellow.

3. Pharmaceutical form

Tablets for oral administration

4. Clinical particulars

4.1 Therapeutic indications

Sparfloxacin is indicated for the treatment of adults (≥ 18 years of age) with the following infections caused by susceptible strains of the designated microorganisms:

Community-acquired pneumonia caused by Chlamydia pneumoniae, Haemophilus influenzae, Haemophilus parainfluenzae, Moraxella catarrhalis, Mycoplasma pneumoniae, or Streptococcus pneumoniae

Acute bacterial exacerbations of chronic bronchitis caused by Chlamydia pneumoniae, Enterobacter cloacae, Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Moraxella catarrhalis, Staphylococcus aureus, or Streptococcus pneumonia.

Appropriate culture and susceptibility tests should be performed before treatment in order to isolateand identify organisms causing the infection and to determine their susceptibility to sparfloxacin. Therapy with sparfloxacin may be initiated before results of these tests are known; once results become available, appropriate therapy should be selected.

Culture and susceptibility testing performed periodically during therapy will provide information on the continued susceptibility of the pathogen to the antimicrobial agent and also on the possible emergence of bacterial resistance.

4.2 Posology and method of administration

Posology

Sparfloxacin can be taken with or without food.

Antacids containing magnesium and aluminum or sucralfate or Videx®, (Didanosine), chewable/buffered tablets or the pediatric powder for oral solution may be taken 4 hours after administration of Sparfloxacin Tablets.

The recommended daily dose of Sparfloxacin in patients with normal renal function is two 200-mg tablets taken on the first day as a loading dose. Thereafter, one 200-mg tablet should be taken every 24 hours for a total of 10 days of therapy (11 tablets). The recommended daily dose of sparfloxacin in patients with renal impairment (creatinine clearance < 50 mL/min) is two 200-mg tablets taken on the first day as a loading dose. Thereafter, one 200-mg tablet should be taken every 48 hours for a total of 9 days of therapy (6 tablets).

Method of administration

For oral use.

4.3 Contraindications

Sparfloxacin is contraindicated for individuals with a history of hypersensitivity or photosensitivity reactions.

Torsade de pointes has been reported in patients receiving sparfloxacin concomitantly with disopyramide and amiodarone. Consequently, sparfloxacin is contraindicated for individuals receiving these drugs as well as other QTc-prolonging antiarrhythmic drugs reported to cause torsade de pointes, such as class Ia antiarrhythmic agents (e.g., quinidine, procainamide), class III antiarrhythmic agents (e.g., sotalol), and bepridil. Sparfloxacin is contraindicated in patients with known QTc prolongation or in patients being treated concomitantly with medications known to produce an increase in the QTc interval and/or torsade de pointes (e.g., terfenadine).

It is essential to avoid exposure to the sun, bright natural light, and UV rays throughout the entire duration of treatment and for 5 days after treatment is stopped. Sparfloxacin is contraindicated in patients whose life-style or employment will not permit compliance with required safety precautions concerning phototoxicity.

4.4 Special warnings and precautions for use

Warning

Moderate to severe phototoxic reactions have occurred in patients exposed to direct or indirect sunlight or to artificial ultraviolet light (e.g., sunlamps) during or following treatment. these reactions have also occurred in patients exposed to shaded or diffuse light, including exposure through glass or during cloudy weather. patients should be advised to discontinue sparfloxacin therapy at the first signs or symptoms of a phototoxicity reaction such as a sensation of skin burning, redness, swelling, blisters, rash, itching, or dermatitis.

The overall incidence of drug related phototoxicity in the 1585 patients who received sparfloxacin during clinical trials with recommended dosage was 7.9% (n=126). Phototoxicity ranged from mild 4.1% (n=65) to moderate 3.3% (n=52) to severe 0.6% (n=9), with severe defined as involving at least significant curtailment of normal daily activity. The frequency of phototoxicity reactions characterized by blister formation was 0.8% (n=13) of which 3 were severe. The discontinuation rate due to phototoxicity independent of drug relationship was 1.1% (n=17).

As with some other types of phototoxicity, there is the potential for exacerbation of the reaction on re-exposure to sunlight or artificial ultraviolet light prior to complete recovery from the reaction. In a few cases, recovery from phototoxicity reactions was prolonged for several weeks. In rare cases, reactions have recurred up to several weeks after stopping sparfloxacin therapy.

Exposure to direct and indirect sunlight (even when using sunscreens or sunblocks) should be avoided while taking sparfloxacin and for five days following therapy. sparfloxacin therapy should be discontinued immediately at the first signs or symptoms of phototoxicity.

These phototoxic reactions have occurred with and without the use of sunscreens or sunblocks and have been associated with a single dose of sparfloxacin. However, a study in healthy volunteers has demonstrated that some sunscreen products, specifically those active in blocking UVA spectrum wavelengths (those containing the active ingredients octocrylene or Parsol® 1789), can moderate the photosensitizing effect of sparfloxacin. However, many over-the-countersunscreens do not provide adequate UVA protection.

Increases in the QTc interval have been observed in healthy volunteers treated with sparfloxacin. After a single loading dose of 400 mg, a mean increase in QTc interval of 11 msec (2.9%) is seen; at steady-state the mean increase is 7 msec (1.9%). The magnitude of the QTc effect does not increase with repeated administration, and the QTc returns to baseline within 48 hours of the last dose. In clinical trials involving 1489 patients with a baseline QTc measurement, the mean prolongation at steady-state was 10 msec (2.5%); 0.7% of patients had a QTc interval greater than 500 msec; however, no arrhythmic effects were seen.

In a covariate analysis, age did not have a statistically significant contribution to the change in QTcrecorded in patients taking sparfloxacin. However, in controlled clinical trials, QTc interval prolongation was more frequently reported as an adverse event in patients ≥ 65 years of age than in younger patients. In these clinical trials, QTc interval prolongation was reported more frequently as an adverse event (defined as QTc ≥ 0.440 sec or ≥ 15% change from baseline) in elderly patients treated with sparfloxacin than in elderly patients treated with a comparator drug. During post marketing surveillance, cardiovascular events including torsades de pointes and other arrhythmias were more frequent in the elderly than in younger patients treated with sparfloxacin although a history of underlying cardiac disease in this population was more common. Sparfloxacin is contraindicated in patients with known QTc prolongation.

Convulsions and toxic psychoses have been reported in patients receiving quinolones, including sparfloxacin. Quinolones may also cause increased intracranial pressure and central nervous systemstimulation which may lead to tremors, restlessness/agitation, anxiety/nervousness, lightheadedness, confusion, hallucinations, paranoia, depression, nightmares, insomnia, and, rarely, suicidal thoughts or acts. These reactions may occur following the first dose. If these reactions occur in patients receiving sparfloxacin, the drug should be discontinued and appropriate measures instituted. As with other quinolones, sparfloxacin should be used with caution in patients with a known or suspected CNS disorder that may predispose to seizures or lower the seizure threshold (e.g., severe cerebral arteriosclerosis, epilepsy) or in the presence of other risk factors that may predispose to seizures or lower the seizure threshold (e.g., certain drug therapy, renal dysfunction). Cases of seizure associated with hypoglycemia have been reported.

Serious and occasionally fatal hypersensitivity (including anaphylactoid or anaphylactic) reactions, some following the first dose, have been reported in patients receiving quinolones. Some reactions were accompanied by cardiovascular collapse, hypotension/shock, seizure, loss of consciousness, tingling, angioedema (including tongue, laryngeal, throat, or facial edema), airway obstruction(including bronchospasm, shortness of breath, and acute respiratory

distress), dyspnea, urticaria, and/or itching. Only a few patients had a history of previous hypersensitivity reactions. If an allergic reaction to sparfloxacin occurs, the drug should be discontinued immediately. Serious acute hypersensitivity reactions may require immediate treatment with epinephrine, and other resuscitative measures including oxygen, intravenous fluids, antihistamines, corticosteroids, pressor amines, and airway management, including intubation, as clinically indicated.

Serious and sometimes fatal events, some due to hypersensitivity, and some due to uncertain etiology, have been reported rarely in patients receiving therapy with quinolones. These events may be severe and generally occur following the administration of multiple doses.

Clinical manifestations may include one or more of the following: fever, rash or severe dermatologic reactions (e.g., toxic epidermal necrolysis, Stevens-Johnson Syndrome); vasculitis; arthralgia; myalgia; serum sickness; allergic pneumonitis; interstitial nephritis; acute renal insufficiency or failure; hepatitis; jaundice; acute hepatic necrosis or failure; anemia, including hemolytic and aplastic; thrombocytopenia, including thrombotic thrombocytopenic purpura; leukopenia; agranulocytosis; pancytopenia; and/or other hematologic abnormalities. The drug should be discontinued immediately at the first appearance of a skin rash or any other sign of hypersensitivity and supportive measures instituted.

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including sparfloxacin, and may range in severity from mild to lifethreatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by Clostridium difficile is one primary cause of "antibiotic-associated colitis."

After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against C. difficile colitis.

Ruptures of the shoulder, hand, and Achilles tendons that required surgical repair or resulted in prolonged disability have been reported with sparfloxacin and other quinolones. Sparfloxacin 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 confidently excluded. Tendon rupture can occur at any time during or after therapy with sparfloxacin.

Precaution:

General

Adequate hydration of patients receiving sparfloxacin should be maintained to prevent the formation of a highly concentrated urine.

Administer sparfloxacin with caution in the presence of renal insufficiency. Careful clinical observation and appropriate laboratory studies should be performed prior to and during therapy since elimination of sparfloxacin may be reduced. Adjustment of the dosage regimen is necessary for patients with impaired renal function-creatinine clearance < 50 mL/min.

Avoid the concomitant prescription of medications known to prolong the QT_c interval, *e.g.*, erythromycin, terfenadine, astemizole, cisapride, pentamidine, tricyclic antidepressants, some antipsychotics including phenothiazines.

Sparfloxacin is not recommended for use in patients with pro-arrhythmic conditions (*e.g.*, hypokalemia, significant bradycardia, congestive heart failure, myocardial ischemia, and atrial fibrillation).
Moderate to severe phototoxicity reactions have been observed in patients exposed to direct sunlight while receiving drugs in this class. Excessive exposure to sunlight should be avoided. In clinical trials with sparfloxacin, phototoxicity was observed in approximately 7% of patients. Therapy should be discontinued if phototoxicity (*e.g.*, a skin eruption) occurs.
As with other quinolones, sparfloxacin should be used with caution in any patient with a known or suspected CNS disorder that may predispose to seizures or lower the seizure threshold (*e.g.*, severe cerebral arteriosclerosis, epilepsy) or in the presence of other risk factors that may predispose to seizures or lower the seizure threshold (*e.g.*, certain drug therapy, renal dysfunction).

4.5 Interaction with other medicinal products and other forms of interaction

Digoxin
Sparfloxacin has no effect on the pharmacokinetics of digoxin.
Methylxanthines
Sparfloxacin does not increase plasma theophylline concentrations. Since there is no interaction with theophylline, interaction with other methylxanthines such as caffeine is unlikely.
Warfarin
Sparfloxacin does not increase the anti-coagulant effect of warfarin.
Cimetidine
Cimetidine does not affect the pharmacokinetics of sparfloxacin.
Antacids and Sucralfate
Aluminum and magnesium cations in antacids and sucralfate form chelation complexes with sparfloxacin. The oral bioavailability of sparfloxacin is reduced when an aluminum-magnesium suspension is administered between 2 hours before and 2 hours after sparfloxacin administration. Similarly, the oral bioavailability of sparfloxacin may be reduced when Videx®, (Didanosine), chewable/buffered tablets or the pediatric powder for oral solution is administered between 2 hours before and 2 hours after sparfloxacin administration. The oral bioavailability of sparfloxacin is not reduced when the aluminum-magnesium suspension is administered 4 hours following sparfloxacin administration.
Zinc/iron salts
Absorption of quinolones is reduced significantly by these preparations. These products may be taken 4 hours after sparfloxacin administration.
Probenecid
Probenecid does not alter the pharmacokinetics of sparfloxacin.
Drug/Laboratory Test Interactions
Sparfloxacin therapy may produce false negative culture results for Mycobacterium tuberculosis by suppression of mycobacterial growth.

4.6 Pregnancy and lactation

Pregnancy

Teratogenic Effects
Pregnancy Category C:Reproduction studies performed in rats, rabbits, and monkeys at oral doses 6.2, 4.4, and 2.6 times higher than the maximum human dose, respectively, based upon mg/m² (corresponding to plasma concentrations 4.5- and 6.5-fold higher than in humans in the monkey and

rat, respectively) did not reveal any evidence of teratogenic effects. At these doses, sparfloxacin was clearly maternally toxic to the rabbit and monkey with evidence of slight maternal toxicity observed in the rat. When administered to pregnant rats at clearly maternally toxic doses (≥ 9.3 times the maximum human dose based upon mg/m²), sparfloxacin induced a dose-dependent increase in the incidence of fetuses with ventricular septal defects. Among the three species tested, this effect was specific to the rat. There are, however, no adequate and well-controlled studies in pregnant women. Sparfloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

Sparfloxacin is excreted in human milk. Because of the potential for serious adverse reactions in infants nursing from mothers taking sparfloxacin, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in pediatric patients and adolescents under the age of 18 years have not been established. Quinolones, including sparfloxacin, cause arthropathy and osteochondrosis in juvenile animals of several species.

Geriatric Use

In controlled clinical trials conducted in the United States and Europe, sparfloxacin tablets have been administered to approximately 458 elderly (∃65 years of age) patients. It is known that the QTcinterval increases with increasing age. In a covariate analysis, age did not have a statistically significant contribution to the change in QTc recorded in patients taking sparfloxacin. However, in controlled clinical trials, QTc interval prolongation was more frequently reported as an adverse event in patients ∃65 years of age than in younger patients. In addition, QTc interval prolongation was reported more frequently as an adverse event (defined as QTc ∃0.440 sec or ∃15% change from baseline) in sparfloxacin treated elderly patients (7/314) than elderly patients treated with a comparator drug (0/301). Finally, the majority of patients with postmarketing cardiovascular events were elderly; however, it is not possible to exclude the roles of other contributing factors such as underlying cardiovascular diseases and concomitant medications. There were no other apparent overall differences in safety and efficacy observed between the elderly and younger individuals in controlled clinical trials. Other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Sparfloxacin is known to be excreted renally and the risk of adverse reactions 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.

4.7 Effects on ability to drive and use machines

sparfloxacin may cause neurologic adverse effects (*e.g.*, dizziness, lightheadedness) and that patients should know how they react to sparfloxacin before they operate an automobile or machinery or engage in other activities requiring mental alertness and coordination.

4.8 Undesirable effects

In clinical trials, most of the adverse events were mild to moderate in severity and transient in nature. During clinical investigations with the recommended dosage, 1585 patients received sparfloxacin and 1331 patients received a comparator. The discontinuation rate due to adverse events

was 6.6% for sparfloxacin versus 5.6% for cefaclor, 14.8% for erythromycin, 8.9% for ciprofloxacin, 7.4% for ofloxacin, and 8.3% for clarithromycin.

The most frequently reported events (remotely, possibly, or probably drug related with an incidence of ≥ 1%) among sparfloxacin treated patients in the US phase 3 clinical trials with the recommended dosage were: photosensitivity reaction (7.9%), diarrhea (4.6%), nausea (4.3%), headache (4.2%), dyspepsia (2.3%), dizziness (2.0%), insomnia (1.9%), abdominal pain (1.8%),pruritus(1.8%) , taste perversion (1.4%), and QTc interval prolongation (1.3%), vomiting (1.3%), flatulence (1.1%), and vasodilatation (1.0%).
In US phase 3 clinical trials of shorter treatment duration than the recommended dosage, the most frequently reported events (incidence ≥ 1%, remotely, possibly, or probably drug related) were: headache (8.1%), nausea (7.6%), dizziness (3.8%), photosensitivity reaction (3.6%), pruritus (3.3%), diarrhea (3.2%), vaginal moniliasis (2.8%), abdominal pain (2.4%), asthenia (1.7%), dyspepsia (1.6%), somnolence (1.5%), dry mouth (1.4%), and rash (1.1%).

4.9 Overdose

In case of overdosage, the patient should be monitored in a suitably equipped medical facility and advised to avoid sun exposure for five days. ECG monitoring is recommended due to the possible prolongation of the QTc interval. There is no known antidote for sparfloxacin overdosage.
It is not known whether sparfloxacin is dialyzable.
Single doses of sparfloxacin were relatively non-toxic via the oral route of administration in mice, rats, and dogs. No deaths occurred within a 14-day posttreatment observation period at the highest oral doses tested, up to 5000 mg/kg in either rodent species, or up to 600 mg/kg in the dog. Clinical signs observed included inactivity in mice and dogs, diarrhea in both rodent species, and vomiting, salivation, and tremors in dogs.

5. Pharmacological properties

Pharmacotherapeutic group: Quinolone Antibacterials, Fluoroquinolones. ATC code: J01 MA 09

Sparfloxacin has in vitro activity against a wide range of gram-negative and gram-positive microorganisms. Sparfloxacin exerts its antibacterial activity by inhibiting DNA gyrase, a bacterialtopoisomerase. DNA gyrase is an essential enzyme which controls DNA topology and assists in DNA replication, repair, deactivation, and transcription.
Quinolones differ in chemical structure and mode of action from β-lactam antibiotics. Quinolones may, therefore, be active against bacteria resistant to β-lactam antibiotics.
Although cross-resistance has been observed between sparfloxacin and other fluoroquinolones, some microorganisms resistant to other fluoroquinolones may be susceptible to sparfloxacin.
In vitro tests show that the combination of sparfloxacin and rifampin is antagonistic against Staphylococcus aureus.
Sparfloxacin has been shown to be active against most strains of the following microorganisms, both in vitro and in clinical infections:

Aerobic gram-positive microorganisms

Staphylococcus aureus
Streptococcus pneumoniae (penicillin-susceptible strains)

Aerobic gram-negative microorganisms

Enterobacter cloacae
Haemophilus influenzae
Haemophilus parainfluenzae

Klebsiella pneumoniae
Moraxella catarrhalis
Other microorganisms
Chlamydia pneumoniae
Mycoplasma pneumonia
The following in vitro data are available, but their clinical significance is unknown:
Sparfloxacin exhibits in vitro minimal inhibitory concentrations (MICs) of 1 µg/mL or less against most (≥ 90%) strains of the following microorganisms; however, the safety and effectiveness of sparfloxacin in treating clinical infections due to these microorganisms have not been established in adequate and well controlled clinical trials.
Aerobic gram-positive microorganisms
Streptococcus agalactiae
Streptococcus pneumoniae (penicillin-resistant strains)
Streptococcus pyogenes
Viridans group streptococci
Aerobic gram-negative microorganisms
Acinetobacter anitratus
Acinetobacter lwoffi
Citrobacter diversus
Enterobacter aerogenes
Klebsiella oxytoca
Legionella pneumophila
Morganella morganii
Proteus mirabilis
Proteus vulgaris

5.2 Pharmacokinetic properties

Absorption

Sparfloxacin is well absorbed following oral administration with an absolute oral bioavailability of 92%. The mean maximum plasma sparfloxacin concentration following a single 400-mg oral dose was approximately 1.3 (±0.2) µg/mL. The area under the curve (mean AUC0→∞) following a single 400-mg oral dose was approximately 34 (±6.8) µg•hr/mL.
Maximum plasma concentrations for the initial oral 400-mg loading dose were typically achieved between 3 to 6 hours following administration with a mean value of approximately 4 hours. Maximum plasma concentrations for a 200-mg dose were also achieved between 3 to 6 hours after administration with a mean of about 4 hours.
Oral absorption of sparfloxacin is unaffected by administration with milk or food, including high fat meals. Concurrent administration of antacids containing magnesium hydroxide and aluminum hydroxide reduces the oral bioavailability of sparfloxacin by as much as 50%.

Distribution

Upon reaching general circulation, sparfloxacin distributes well into the body, as reflected by the large mean steady-state volume of distribution (Vdss) of 3.9 (±0.8) L/kg. Sparfloxacin exhibits low plasma protein binding in serum at about 45%.
Sparfloxacin penetrates well into body fluids and tissues. Results of tissue and body fluid distribution studies demonstrated that oral administration of sparfloxacin produces sustained concentrations and that sparfloxacin concentrations in lower respiratory tract tissues and fluids

generally exceed the corresponding plasma concentrations. The concentration of sparfloxacin in respiratory tissues (pulmonary parenchyma, bronchial wall, and bronchial mucosa) at 2 to 6 hours following standard oral dosing was approximately 3 to 6 times greater than the corresponding concentration in plasma. Concentrations in these respiratory tissues increase at up to 24 hours following dosing. Sparfloxacin is also highly concentrated into alveolar macrophages compared to plasma. Mean pleural effusion to plasma concentration ratios were 0.34 and 0.69 at 4 and 20 hours postdose, respectively.

Metabolism

Sparfloxacin is metabolized by the liver, primarily by phase II glucuronidation, to form a glucuronide conjugate. Its metabolism does not utilize or interfere with cytochrome-mediated oxidation, in particular cytochrome P450.

Excretion

The total body clearance and renal clearance of sparfloxacin were 11.4 (±3.5) and 1.5 (±0.5) L/hr, respectively. Sparfloxacin is excreted in both the feces (50%) and urine (50%). Approximately 10% of an orally administered dose is excreted in the urine as unchanged drug in patients with normal renal function. Following a 400-mg loading dose of sparfloxacin, the mean urine concentration 4 hours postdose was in excess of 12.0 μg/mL, and measurable concentrations of active drug persisted through six days for subjects with normal renal function.

The terminal elimination phase half-life (t1/2) of sparfloxacin in plasma generally varies between 16 and 30 hours, with a mean t1/2of approximately 20 hours. The t1/2 is independent of the administered dose, suggesting that sparfloxacin elimination kinetics are linear.

Special Populations

Geriatric: The pharmacokinetics of sparfloxacin are not altered in the elderly with normal renal function.

Pediatric: The pharmacokinetics of sparfloxacin in pediatric subjects have not been studied.

Gender: There are no gender differences in the pharmacokinetics of sparfloxacin.

Renal insufficiency: In patients with renal impairment (creatinine clearance < 50 mL/min), the terminal elimination half-life of sparfloxacin is lengthened. Single or multiple doses of sparfloxacin in patients with varying degrees of renal impairment typically produce plasma concentrations that are twice those observed in subjects with normal renal function.

Hepatic insufficiency: The pharmacokinetics of sparfloxacin are not altered in patients with mild or moderate hepatic impairment without cholestasis.

5.3 Preclinical safety data

None Known.

6. Pharmaceutical particulars

6.1 List of excipients

Microcrystalline Cellulose, Povidone, Isopropyl alcohol, Magnesium Stearate, Talc, Sodium starch glycolate, Croscarmellose sodium, Colloidal Silicon dioxide, AF Coat Non Aqeous Exrra white, Colour Quinoline yellow, Dichloromethane and Isopropyl alcohol.

6.2 Incompatibilities

Not Applicable.

6.3 Shelf life
36 Months

6.4 Special precautions for storage
Store in a dark & dry place below 30°C.

6.5 Nature and contents of container
1x 10's Tablets are packed in a monocarton along with pack Insert and such 10 monocartons are packed in an outer carton.

6.6 Special precautions for disposal and other handling
No Special precautions

7. Manufacturer:
Scott-Edil Pharmacia Limited,
56, EPIP, Phase-I, Jharmajri,
Baddi, Distt. Solan- 173205 (H.P)
INDIA

8. Marketing Authorization Holder
SIMPEC PHARMACEUTICAL LTD.
No. 2 Ajaegbue Street-Fegge Onitsha,
Anambra State Nigeria,

9. Date of revision of the text
February 2021

10. DOSIMETRY (IF APPLICABLE)
Not applicable

11. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)
Not Applicable