Summary Product Characteristics

1. **Name of the Medicinal product:** **SASTEK** TRAMADOL 100 MG TABLETS
(Tramadol Tablets 100 mg)

Route of Administration: Oral

2. **Qualitative and Quantitative composition: Each uncoated tablet contains :**
Tramadol Hydrochloride Bp 100mg
Excipients q.s.

Sr. No.	Ingredients	Specification	Label claim	Quantity /tablet (mg)	% Over ages	Reason of inclusion
Active						
1.	Tramadol Hydrochloride	BP	100.0 mg	100.00	Nil	Active
Excipients						
2.	M.C.C.P.(PH-102)	BP	---	193.00	Nil	Diluent
3.	Base Granules (Starch & DCP)	IH	---	19.00	Nil	Diluent
4.	Magnesium Stearate	BP	---	4.00	Nil	Lubricant
5.	Croscarmellose sodium	BP	---	6.00	Nil	Disintegrant
6.	Purified Talc	BP	---	6.00	Nil	Glidant
7.	Colloidal anhydrous silica	BP	---	2.00	Nil	Lubricant
8.	Purified Water	BP	---	q.s.	Nil	Solvent
Core tablet weight				**330.00**		

BP: British Pharmacopoeia
IH: In-House
q.s.: Quantity Sufficient

3. Pharmaceutical Form: Uncoated tablet (White coloured, Circular shaped, Flat face,bevelled edged, Uncoated tablets having an embossing 100 on one side and + on the other side of each tablets.

4. Clinical Particulars:

4.1 Therapeutic Indications:

Tramadol Tablets is indicated for the management of moderate to moderately severe pain in adults.

4.2 Posology and method of administration:

Adults (17 years of age and over)

For patients with moderate to moderately severe chronic pain not requiring rapid onset of analgesic effect, the tolerability of Tramadol Tablets with the following titration regimen: Tramadol Tablets can be improved by initiating therapy should be started at 25 mg/day qAM and titrated in 25 mg increments as separate doses every 3 days to reach 100 mg/day (25 mg q.i.d.). Thereafter the total daily dose may be increased by 50 mg as tolerated every 3 days to reach 200 mg/day (50 mg q.i.d.). After titration, Tramadol Tablets 50 to 100 mg can be administered as needed for pain relief every 4 to 6 hours not to exceed 400 mg/day.

For the subset of patients for whom rapid onset of analgesic effect is required and for whom the benefits outweigh the risk of discontinuation due to adverse events associated with higher initial doses, Tramadol Tablets

50 mg to 100 mg can be administered as needed for pain relief every four to six hours, not to exceed 400 mg per day.

Individualization of Dose

Good pain management practice dictates that the dose be individualized according to patient need using the lowest beneficial dose. Studies with tramadol in adults have shown that starting at the lowest possible dose and titrating upward will result in fewer discontinuations and increased tolerability.

- In all patients with creatinine clearance less than 30 mL/min, it is recommended that the dosing interval of Tramadol Tablets be increased to 12 hours, with a maximum daily dose of 200 mg. Since only 7% of an administered dose is removed by hemodialysis, dialysis patients can receive their regular dose on the day of dialysis.
- The recommended dose for adult patients with cirrhosis is 50 mg every 12 hours.
- In general, dose selection for an elderly patient over 65 years old should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function and of concomitant disease or other drug therapy. For elderly patients over 75 years old, total dose should not exceed 300 mg/day.

4.3 Contraindications

Tramadol Tablets should not be administered to patients who have previously demonstrated hypersensitivity to tramadol, any other component of this product or opioids. Tramadol Tablets is contraindicated in any situation where opioids are contraindicated, including acute intoxication with any of the following: alcohol, hypnotics, narcotics, centrally acting analgesics, opioids or psychotropic drugs. Tramadol Tablets may worsen central nervous system and res piratory depression in these patients.

4.4 Special warnings and precautions for use

Warnings:

Seizure Risk within the recommended dosage range. Spontaneous post-marketing reports indicate that Seizures have been reported in patients receiving Tramadol Tablets seizure risk is increased with doses of Tramadol Tablets above the recommended range. Concomitant use of Tramadol Tablets increases the seizure risk in patients taking:

- Selective serotonin re-uptake inhibitors (SSRI antidepressants or anorectics),

• Tricyclic antidepressants (TCAs), and other tricyclic compounds (e.g., cyclobenzaprine , promethazine, etc.), or Other opioids. Administration of Tramadol Tablets may enhance the seizure risk in patients taking:
• MAO inhibitors
• Neuroleptics, or
• Other drugs that reduce the seizure threshold.
Risk of convulsions may also increase in patients with epilepsy, those with a history of seizures, or in patients with a recognized risk for seizure (such as head trauma, metabolic disorders, alcohol and drug withdrawal, CNS infections) . In Tramadol Tablets overdose, naloxone administration may increase the risk of seizure.

Precautions:

Acute Abdominal Conditions

The administration of Tramadol Tablets may complicate the clinical assessment of patients with acute abdominal conditions.

Use in Renal and Hepatic Disease

Impaired renal function results in a decreased rate and extent of excretion of tramadol and its active metabolite, M1. In patients with creatinine clearances of less than 30 mL/min, dosing reduction is recommended.
Metabolism of tramadol and M1 is reduced in patients with advanced cirrhosis of the liver. In cirrhotic patients, dosing reduction is recommended. With the prolonged half-life in these conditions, achievement of steady-state is delayed, so that it may take several days for elevated plasma concentrations to develop.

Information for Patients

• Patients should be informed that Tramadol Tablets may cause seizures and/or serotonin syndrome with concomitant use of serotonergic agents (including SSRIs, SNRIs, and triptans) or drugs that significantly reduce the metabolic clearance of tramadol.
• Tramadol Tablets may impair mental or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery.
• Tramadol Tablets should not be taken with alcohol containing beverages. should be used with caution when taking medications such as tranquilizers, hypnotics or other opiate containing analgesics.
• The patient should be instructed to inform the physician if they are pregnant, think they might become pregnant, or are trying to become pregnant
• The patient should understand the single-dose and 24-hour dose limit and the time interval between doses, since exceeding these recommendations can result in respiratory depression, seizures and death.

4.5 Interaction with other medicinal products and other forms of interaction:

CYP2D6 and CYP3A4 Inhibitors Concomitant administration of CYP2D6 and/or CYP3A4 inhibitors, such as quinidine, fluoxetine, paroxetine and amitriptyline (CYP2D6 inhibitors), and ketoconazole and erythromycin (CYP3A4 inhibitors), may reduce metabolic clearance of tramadol increasing the risk for serious adverse events including seizures and serotonin syndrome.
Serotonergic Drugs There have been postmarketing reports of serotonin syndrome with use of tramadol and SSRIs/SNRIs or MAOIs and a2-adrenergic blockers. Caution is advised when

Tramadol Tablets is coadministered with other drugs that may affect the serotonergic neurotransmitter systems, such as SSRIs, MAOIs, triptans, linezolid (an antibiotic which is a reversible non-selective MAOI), lithium, or St. John's Wort. If concomitant treatment of Tramadol Tablets with a drug affecting the serotonergic neurotransmitter system is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases.

Triptans

Based on the mechanism of action of tramadol and the potential for serotonin syndrome, caution is advised when Tramadol Tablets is coadministered with a triptan. If concomitant treatment of Tramadol Tablets with a triptan is clinically warranted, careful observation of the 1qq`patient is advised, particularly during treatment initiation and dose increases.

Use with Carbamazepine

Patients taking carbamazepine may have a significantly reduced analgesic effect of Tramadol Tablets. Because carbamazepine increases tramadol metabolism and because of the seizure risk associated with tramadol, concomitant administration of Tramadol Tablets and carbamazepine is not recommended.

Use with Quinidine

Tramadol is metabolized to M1 by CYP2D6. Quinidine is a selective inhibitor of that results in increased concentrations of tramadol and reduced concentrations of M1. The clinical consequences of these findings are unknown. *In vitro* drug interaction studies in human liver microsomes indicate that tramadol has no effect on quinidine metabolism. isoenzyme, so that concomitant administration of quinidine and Tramadol Tablets.

Potential for Other Drugs to Affect Tramadol

In vitro drug interaction studies in human liver microsomes indicate that concomitant administration with inhibitors of CYP2D6 such as fluoxetine, paroxetine, and amitriptyline could result in some inhibition of the metabolism of tramadol. Administration of CYP3A4 inhibitors, such as ketoconazole and erythromycin, or inducers, such as rifampin and St. John's Wort, with Tramadol Tablets may affect the metabolism of tramadol leading to alteted tramadol exposure.

Potential for Tramadol to Affect Other Drugs

In vitro studies indicate that tramadol is unlikely to inhibit the CYP3A4-mediated metabolism of other drugs when tramadol is administered concomitantly at therapeutic doses. Tramadol does not appear to induce its own metabolism in humans, since observed maximal plasma concentrations after multiple oral doses are higher than expected based on single-dose data. Tramadol is a mild inducer of selected drug metabolism pathways measured in animals.

Use with Cimetidine

Concomitant administration of Tramadol Tablets with cimetidine does not result in clinically significant changes in tramadol pharmacokinetics. Therefore, no alteration of the

Tramadol Tablets dosage regimen is recommended.

Use with Digoxin and Warfarin

Post-marketing surveillance has revealed rare reports of digoxin toxicity and alteration of warfarin effect, including elevation of prothrombin times.

Carcinogenesis, Mutagenesis, Impairment of Fertility

A slight, but statistically significant, increase in two common murine tumors, pulmonary and hepatic, was observed in a mouse carcinogenicity study, particularly in aged mice. Mice were dosed orally up to 30 mg/kg (90 mg/m^{2}or 0.36 times the maximum daily human dosage of 246

mg/m^2) for approximately two years, although the study was not done with the Maximum Tolerated Dose. This finding is not believed to suggest risk in humans. No such finding occurred in a rat carcinogenicity study (dosing orally up to 30 mg/kg, 180 mg/m^2 , or 0.73 times the maximum daily human dosage).

Tramadol was not mutagenic in the following assays: Ames *Salmonella* microsomal activation test, CHO/HPRT mammalian cell assay, mouse lymphoma assay (in the absence of metabolic activation), dominant lethal mutation tests in mice, chromosome aberration test in Chinese hamsters, and bone marrow micronucleus tests in mice and Chinese hamsters. Weakly mutagenic results occurred in the presence of metabolic activation in the mouse lymphoma assay and micronucleus test in rats. Overall, the weight of evidence from these tests indicates that tramadol does not pose a genotoxic risk to humans.

No effects on fertility were observed for tramadol at oral dose levels up to 50 mg/kg (300 mg/m ^{2}) in male rats and 75 mg/kg (450 mg/m^2) in female rats. These dosages are 1.2 and 1.8 times the maximum daily human dosage of 246 mg/m^2, respectively.

4.6 Pregnancy and Lactation:

Teratogenic Effects: Pregnancy Category C

Tramadol has been shown to be embryotoxic and fetotoxic in mice, (120 mg/kg or 360 mg/m^2), rats (=25 mg/kg or 150 mg/m^2) and rabbits (=75 mg/kg or 900 mg/m) at maternally toxic dosages, but was not teratogenic at these dose levels. These dosages on a mg/m^2 basis are 1.4, =0.6, and =3.6 times the maximum daily human dosage (246mg/m^2) for mouse, rat and rabbit, respectively. No drug-related teratogenic effects were observed in progeny of mice (up to 140 mg/kg or 420 mg/m^2), rats (up to 80 mg/kg or 480 mg/m$_2$) or rabbits (up to 300 mg/kg or 3600mg/m^2) treated with tramadol by various routes. Embryo and fetal toxicity consisted primarily of decreased fetal weights, skeletal ossification and increased supernumerary ribs at maternally toxic dose levels. Transient delays in developmental or behavioral parameters were also seen in pups from rat dams allowed to deliver. Embryo and fetal lethality were reported only in one rabbit study at 300 mg/kg (3600 mg/m^2), a dose that would cause extreme maternal toxicity in the rabbit. The dosages listed for mouse, rat and rabbit are 1.7, 1.9 and 14.6 times the maximum daily human dosage (246 mg/m), respectively.

Non-teratogenic Effects

Tramadol was evaluated in peri- and post-natal studies in rats. Progeny of dams receiving oral (gavage) dose levels of 50 mg/kg (300 mg/m or 1.2 times the maximum daily human tramadol dosage) or greater had decreased weights, and pup survival was decreased early in lactation at 80 mg/kg (480 mg/m^2 or 1.9 and higher the maximum daily human dose).

There are no adequate and well-controlled studies in pregnant women. Tramadol Tablets. Should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Neonatal seizures, neonatal withdrawal syndrome, fetal death and still birth have been reported during post-marketing.

Labor and Delivery

Tramadol Tablets should not be used in pregnant women prior to or during labor unless the potential benefits outweigh the risks. Safe use in pregnancy has not been established. Chronic use during pregnancy may lead to physical dependence and post-partum withdrawal symptoms in the newborn. Tramadol has been shown to cross the placenta. The mean ratio of serum tramadol in the umbilical veins compared to maternal veins was 0.83 for 40 women given Tramadol during labor.

The effect of Tramadol Tablets, if any, on the later growth, development, and functional maturation of the child is unknown.

Nursing Mothers

Tramadol Tablets is not recommended for obstetrical preoperative medication or for post delivery analgesia in nursing mothers because its safety in infants and newborns has not been studied. Following a single IV 100 mg dose of tramadol, the cumulative excretion in breast milk within 16 hours post dose was 100 µg of tramadol (0.1% of the maternal dose) and 27 µg of M1.

Pediatric Use

The safety and efficacy of Tramadol Tablets in patients under 16 years of age have not been established. The use of Tramadol Tablets in the pediatric population is not recommended.

Geriatric Use

In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function and of concomitant disease or other drug therapy. In patients over years of age, daily doses in excess of 300 mg are not recommended.

A total of 455 elderly (65 years of age or older) subjects were exposed to Tramadol Tablets.

In controlled clinical trials. Of those, 145 subjects were 75 years of age and older.

In studies including geriatric patients, treatment-limiting adverse events were higher in subjects over 75 years of age compared to those under 65 years of age. Specifically, 30% of those over 75 years of age had gastrointestinal treatment-limiting adverse events compared to 17% of those under 65 years of age. Constipation resulted in discontinuation of treatment in 10% of those over 75.

4.7 Effects on the ability to drive and use machines

Even when taken according to instructions, tramadol may cause effects such as somnolence and dizziness and therefore may impair the reactions of drivers and machine operators. This applies particularly in conjunction with alcohol and other psychotropic substances.

This medicine can impair cognitive function and can affect a patient's ability to drive safely. This class of medicine is in the list of drugs included in regulations under 5a of the Road Traffic Act 1988. When prescribing this medicine, patients should be told:

• The medicine is likely to affect your ability to drive
• Do not drive until you know how the medicine affects you
• It is an offence to drive while under the influence of this medicine
• However, you would not be committing an offence (called 'statutory defence) if:
- The medicine has been prescribed to treat a medical or dental problem and
- You have taken it according to the instructions given by the prescriber and in the information provided with the medicine and
- It was not affecting your ability to drive safely

4.8 Undesirable effects:

Body as a Whole: Malaise.
Cardiovascular: Vasodilation.
Central Nervous System: Anxiety, Confusion, Coordination disturbance, Euphoria, Miosis, Nervousness, Sleep disorder.
Gastrointestinal: Abdominal pain, Anorexia, Flatulence.
Musculoskeletal: Hypertonia.

Skin: Rash.
Special Senses: Visual disturbance.
Urogenital: Menopausal symptoms, Urinary frequency, Urinary retention.
Incidence less than 1
Ċ*, possibly causally related:* the following lists adverse reactions
that occurred with an incidence of less than 1Ċ in clinical trials and/or reported in post-marketing experience.
Body as a Whole: Accidental injury, Allergic reaction, Anaphylaxis, Death, Suicidal tendency, Weight loss, Serotonin syndrome (mental status change, hyperreflexia, fever, Shivering, tremor, agitation, diaphoresis, seizures and coma).
Cardiovascular: Orthostatic hypotension, Syncope, Tachycardia.
Central Nervous System: Abnormal gait, Amnesia, Cognitive dysfunction, Depression, Difficulty in concentration, Hallucinations, Paresthesia, Seizure.
Tremor.
Respiratory: Dyspnea.
Skin: Stevens-Johnson syndrome/Toxic epidermal necrolysis, Urticaria, Vesicles.
Special Senses: Dysgeusia.
Urogenital: Dysuria, Menstrual disorder.
Other adverse experiences, causal relationship unknown: A variety of other adverse events were reported infrequently in patients taking Tramadol Tablets during clinical trials and/or reported in post-marketing experience. A causal relationship between Tramadol Tablets and these events has not been determined. However, the most significant events are listed below as alerting information to the physician.
Cardiovascular: Abnormal ECG, Hypertension, Hypotension, Myocardial ischemia, Palpitations, Pulmonary edema, pulmonary embolism.
Central Nervous System: Migraine, Speech disorders.
Gastrointestinal: Gastrointestinal bleeding, Hepatitis, Stomatitis, Liver failure.
Laboratory Abnormalities: Creatinine increase, Elevated liver enzymes, Hemoglobin decrease, Proteinuria.
Sensory: Cataracts, Deafness, and Tinnitus.

4.9 Overdose

Acute overdosage with tramadol can be manifested by respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, seizures, bradycardia, hypotension, cardiac arrest, and death. Deaths due to overdose have been reported with abuse and misuse of tramadol, Misuse, Abuse, and Diversion. Review case reports has indicated that the risk of fatal overdose is further increased when tramadol is abused concurrently with alcohol or other CNS depressants, including other opioids.

In the treatment of tramadol overdosage, primary attention should be given to the re-establishment of a patent airway and institution of assisted or controlled ventilation. Supportive measures (including oxygen and vasopressors) should be employed in the management of circulatory shock and pulmonary edema accompanying overdose as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation.

5. Pharmacological Particulars:

5.1 Pharmacodynamic properties
Pharmacotherapeutic group:. Analgesic
ATC code: N02A X02

Mechanism of action
Tramadol Tablets contains tramadol, a centrally acting synthetic opioid analgesic. Although its mode of action is not completely understood, from animal tests, at least two complementary mechanisms appear applicable: binding of parent and M1 metabolite to μ-opioid receptors and weak inhibition of re-uptake of norepinephrine and serotonin. Opioid activity is due to both low affinity binding of the parent compound and higher affinity binding of the O-demethylated metabolite M1 to μ-opioid receptors. In animal models, M1 is up to 6 times more potent than tramadol in producing analgesia and 200 times more potent in μ-opioid binding. Tramadol-induced analgesia is only partially antagonized by the opiate antagonist naloxone in several animal tests. The relative contribution of both tramadol and M1 to human analgesia is dependent upon the plasma concentrations of each compound.
Tramadol has been shown to inhibit reuptake of norepinephrine and serotonin *in vitro,* as have some other opioid analgesics. These mechanisms may contribute independently to the overall analgesic profile of Tramadol Tablets. Analgesia in humans begins approximately within one hour after administration and reaches a peak in approximately two to three hours. Apart from analgesia, Tramadol Tablets administration may produce a constellation of symptoms (including dizziness, somnolence, nausea, constipation, sweating and pruritus) similar to that of other opioids. In contrast to morphine, tramadol has not been shown to cause histamine release. At therapeutic doses, Tramadol Tablets has no effect on heart rate, left-ventricular function or cardiac index. Orthostatic hypotension has been observed.

5.2 Pharmacokinetic properties
Absorption
The mean absolute bioavailability of a 100 mg oral dose is approximately 75%. The mean peak plasma concentration of racemic tramadol and M1 occurs at two and three hours, respectively, after administration in healthy adults. In general, both enantiomers of tramadol and M1 follow a parallel time course in the body following single and multiple doses although small differences (~ 10%) exist in the absolute amount of each enantiomer present.
Distribution
The volume of distribution of tramadol was 2.6 and 2.9 liters/kg in male and female subjects, respectively, following a 100 mg intravenous dose. The binding of tramadol to human plasma proteins is approximately 20% and binding also appears to be independent of concentration up to 10 μg/mL. Saturation of plasma protein binding occurs only at concentrations outside the clinically relevant range.
Metabolism
Tramadol is extensively metabolized after oral administration by a number of pathways, including CYP2D6 and CYP3A4, as well as by conjugation of parent and metabolites. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% of the dose is excreted as metabolites. The remainder is excreted either as unidentified or as unextractable metabolites. The major metabolic pathways appear to be *N*- and *O*-demethylation and glucuronidation or sulfation in the liver. One metabolite (*O*-desmethyltramadol, denoted M1)

is pharmacologically active in animal models. Formation of M1 is dependent on CYP2D6 and as such is subject to inhibition, which may affect the therapeutic response (see
Approximately 7% of the population has reduced activity of the CYP2D6 isoenzyme of cytochrome P-450. These individuals are "poor metabolizers" of debrisoquine, dextromethorphan, tricyclic antidepressants, among other drugs. Based on a population PK analysis of Phase I studies in healthy subjects, concentrations of tramadol were approximately 20% higher in "poor metabolizers" versus "extensive metabolizers", while M1 concentrations were 40% lower. Concomitant therapy with inhibitors of CYP2D6 such as fluoxetine, paroxetine and quinidine could result in significant drug interactions. *In vitro* drug interaction studies in human liver microsomes indicate that inhibitors of CYP2D6 such as fluoxetine and its metabolite norfluoxetine, amitriptyline and quinidine inhibit the metabolism of tramadol to various degrees, suggesting that concomitant administration of these compounds could result in increases in tramadol concentrations and decreased concentrations of M1. The full pharmacological impact of these alterations in terms of either efficacy or safety is unknown. Concomitant use of SEROTONIN reuptake INHIBITORS and MAO INHIBITORS may enhance the risk of adverse events, including seizure and serotonin syndrome.

Elimination

Tramadol is eliminated primarily through metabolism by the liver and the metabolites are eliminated primarily by the kidneys. The mean terminal plasma elimination half-lives of racemic tramadol and racemic M1 are 6.3 ± 1.4 and 7.4 ± 1.4 hours, respectively. The plasma elimination half-life of racemic tramadol increased from approximately six hours to seven hours upon multiple dosing.

5.3 Pre-clinical Safety:

On repeated oral and parenteral administration of tramadol for 6 - 26 weeks in rats and dogs and oral administration for 12 months in dogs, haematological, clinico-chemical and histological investigations showed no evidence of any substance-related changes. Central nervous manifestations only occurred after high doses considerably above the therapeutic range: restlessness, salivation, convulsions, and reduced weight gain. Rats and dogs tolerated oral doses of 20 mg/kg and 10 mg/kg body weight respectively, and dogs rectal doses of 20 mg/kg body weight without any reactions.

In rats tramadol dosages from 50 mg/kg/day upwards caused toxic effects in dams and raised neonate mortality. In the offspring retardation occurred in the form of ossification disorders and delayed vaginal and eye opening. Male fertility was not affected. After higher doses (from 50 mg/kg/day upwards) females exhibited a reduced pregnancy rate. In rabbits there were toxic effects in dams from 125 mg/kg upwards and skeletal anomalies in the offspring.

In some in-vitro test systems there was evidence of mutagenic effects. In-vivo studies showed no such effects. According to knowledge gained so far, tramadol can be classified as non-mutagenic. Studies on the tumorigenic potential of tramadol hydrochloride have been carried out in rats and mice. The study in rats showed no evidence of any substance-related increase in the incidence of tumours. In the study in mice there was an increased incidence of liver cell adenomas in male animals (a dose-dependent, non-significant increase from 15 mg/kg upwards) and an increase in pulmonary tumours in females of all dosage groups (significant, but not dose-dependent).

6. Pharmaceutical Particulars:

6.1 List of Excipients:

M.C.C.P.(PH-102)	BP
Base Granules (Starch & DCP)	IH
Magnesium Stearate	BP
Croscarmellose sodium	BP
Purified Talc	BP
Colloidal anhydrous silica	BP
Purified Water	BP

6.2 Incompatibilities:
None.

6.3 Shelf Life: 36 months

6.4 Special Precautions for storage:
Store below 30°C in a dry place. Protect from light.

6.5 Nature and contents of container:
An Alu-PVC blister of 10 tablets, Such 10 blisters are packed in a primary carton along with pack insert.

6.6 Special precautions for disposal and other handling:
No special requirements.

7. Marketing Authorization Holder:
M/S. SASTEK MEGA PHARMA & CHEMICAL CO. LTD
PLOT NO. 50, ZUNGERU ROAD, SABON GARI,
KANO, NIGERIA

8. Marketing Authorization Number: ---

9. Date of first Authorization /renewal of the authorization: ---

10. Date of revision of text: August 2022