Summary of Product Characteristics

1. Name of the Medicinal Product.

Setroken 8mg tablets

2. Qualitative and Quantitative Information.

Each uncoated orally disintegrating tablet contains ondansetron hydrochloride 8mg tablets.

Excipients with known effect:
Each tablet contains 2.4mg of Aspartame.

For the full list of excipients, see section 6.1

3. Pharmaceutical Form

Orally disintegrating tablets.
A white colour, round shaped, flat, uncoated orally disintegrating tablet having break-line on one side.

4. Clinical Particulars

4.1. Therapeutic Indications

Adults
Ondansetron is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy, and for the prevention and treatment of post-operative nausea and vomiting (PONV).

Paediatric population
Ondansetron is indicated for the management of chemotherapy-induced nausea and vomiting (CINV) in children aged ≥ 6 months, and for the prevention and treatment of PONV in children aged ≥ 1 month.

4.2. Posology and method of administration

Posology
Chemotherapy and Radiotherapy induced nausea and vomiting
The emetogenic potential of cancer treatment varies according to the doses and combinations of chemotherapy and radiotherapy regimens used. Selection of the dose and dosing regimen must therefore be guided by the emetogenic potential.

Adults
The recommended oral dose is 8 mg, taken 1-2 hours prior to chemotherapy or radiation, followed by 8 mg orally every 12 hours over a maximum of 5 days.
In highly emetogenic chemotherapy, a single oral dose up to a maximum of 24 mg ondansetron can be given orally together with 12 mg dexamethasone-21-dihydrogen phosphate disodium salt or equivalent 1 to 2 hours prior to chemotherapy. After the first 24 hours, ondansetron treatment can be continued orally for up to 5 days after a course of treatment. The recommended dose is 8 mg twice daily.
For the prevention of delayed or prolonged emesis, oral treatment is recommended.

Children and adolescents (aged 6 months to 17 years)
The dose for treatment of chemotherapy-induced nausea and vomiting can be calculated on the basis of body surface area (BSA) or based on body weight. In clinical studies with children and adolescents, ondansetron was given as an intravenous infusion, diluted in 25 to 50 mL saline solution or another compatible solution for infusion, over no less than 15 minutes.
Posology based
on body weight results in higher total daily doses compared with posology based on body surface area (see section 5.2).
No data are available from controlled clinical studies on the use of ondansetron for the prevention of delayed, prolonged (protracted) chemotherapy-induced nausea and vomiting. Similarly, no data are available from controlled clinical studies on the use of ondansetron in radiotherapy-induced nausea and vomiting in children.

Posology based on body surface area
Ondansetron should be intravenously administered immediately prior to chemotherapy as an initial dose of 5 mg/m2. The single intravenous dose must not exceed 8mg.
Administration of oral doses can proceed 12 hours later and can be continued for up to 5 days (see table 1).
The total dose within 24 hours (as divided doses) must not exceed the adult dose of 32 mg.
Table 1: Posology based on body surface area in chemotherapy-induced nausea and vomiting (aged 6 months to 17 years)

Body Surface Area	**Day 1**	**Days 2-6**

< 0.6m²	**Initially** 5 mg/m² IV *plus* 2mg ondansetron **after 12 hours**	**Every 12 hours:** 2 mg ondansetron
≥ 0.6 m² to ≤ 1.2 m²	**Initially** 5 mg/m² IV *plus* 4mg ondansetron **after 12 hours**	**Every 12 hours:** 4 mg ondansetron
> 1.2 m²	**Initially** 5 mg/m² IV or 8 mg IV *plus* 8 mg ondansetron **after 12 hours**	**Every 12 hours:** 8 mg ondansetron

Posology based on body weight

Posology based on body weight results in higher total daily doses compared to posology based on surface area (see section 5.2).
Ondansetron should be administered immediately prior to chemotherapy as an initial intravenous single dose of 0.15 mg/kg bodyweight. The single intravenous dose must not exceed 8mg.
If needed, two further intravenous doses can be administered at a 4-hourly interval.
Administration of oral doses can proceed 12 hours later and can be continued over a period of up to 5 days (see Table 2).
The total dose within 24 hours (as divided doses) must not exceed the adult dose of 32 mg.

Table2: Posology based on bodyweight for chemotherapy-induced nausea and vomiting (aged ≥6 months up to 17 years)

Body weight	**Day 1**	**Days 2-6**
≤ 10kg	Up to 3 x 0.15mg/kg doses IV every 4 hours.	2 mg ondansetron every 12 hours
> 10kg	Up to 3 x 0.15mg/kg doses IV every 4 hours.	4 mg ondansetron every 12 hours

Elderly patients
No dose adjustment or change in the dosing frequency is required.

Patients with renal impairment
No alteration of dosage or frequency of dosing, or route of administration is required.

Patients with hepatic impairment
Clearance is significantly reduced and the serum half-life significantly prolonged in patients with moderate to severe impairment of hepatic function. In such patients, a total daily dose of 8 mg ondansetron (oral or intravenous) should not be exceeded.

Patients with poor sparteine/debrisoquine metabolism
The elimination half-life of ondansetron is not altered in patients classified as poor sparteine/debrisoquine metabolizers. Consequently, no difference

in exposure after repeated administration is expected in such patients compared with the general population. No change in the dose or dosing frequency is required.

Post-operative nausea and vomiting (PONV):
Adults
For the prevention of PONV, ondansetron can be administered orally or by intravenous injection. For the prevention of PONV, the recommended dose is 16 mg ondansetron orally 1 hour prior to anesthesia.
For the treatment of established PONV, treatment with ondansetron as a slow intravenous injection is recommended.

Children and adolescents (aged 1 month up to 17 years)
No studies are available on the oral administration of ondansetron for the prophylaxis or treatment of postoperative nausea and vomiting; in this case, a slowly administered intravenous injection (over no less than 30 seconds) is recommended.
For children under 2 years of age, only limited data are available on the use of ondansetron for the treatment of postoperative nausea, nausea and vomiting.

Elderly

There is limited experience in the use of ondansetron in the prevention and treatment of post- operative nausea and vomiting (PONV) in the elderly, however ondansetron is well tolerated in patients over 65 years receiving chemotherapy.

Patients with renal impairment
No alteration of dosage or frequency of dosing, or route of administration is required.

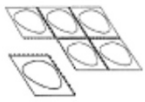
Patients with hepatic impairment
Clearance is significantly reduced and the serum half-life significantly prolonged in patients with moderate or severe impairment of hepatic function. In such patients a total daily dose of 8 mg (oral or intravenous) should not be exceeded.

Patients with poor sparteine/debrisoquine metabolism
The elimination half-life of ondansetron is not altered in patients classified as poor sparteine and debrisoquine metabolizers. Consequently, no difference in exposure after repeated administration is expected in such patients compared with the general population. No change in the dose or dosing frequency is required.

Method of administration
The orally disintegrated tablets should be taken orally. The orally disintegrated tablets should be placed on top of the tongue where it will rapidly disperse and should then be swallowed with water. **Follow these**

instructions carefully:
Do not push the orally disintegrated tablet through the blister.
The tablet(s) must be taken as follows:

In order to stop the tablet from breaking, **do not push** the tablet out of its blister.



Tear along the perforations of the foil to separate off one blister unit.

Remove the covering foil carefully. Start with the corner that is marked with an arrow.

Place the tablet on top of your tongue with dry hands. The tablet will dissolve very quickly, and you should then swallow it with water.

4.3. Contraindications

Concomitant use with apomorphine (see section 4.5).
Hypersensitivity to any component of the preparation

4.4. Special warnings and Precautions for Use

Hypersensitivity reactions have been reported in patients who have exhibited hypersensitivity to other selective 5HT3 receptor antagonists. Respiratory events should be treated symptomatically and clinicians should pay particular attention to them as precursors of hypersensitivity reactions.
Ondansetron prolongs the QT interval in a dose-dependent manner (see section 5.1). In addition, post-marketing cases of Torsade de Pointes have been reported in patients using ondansetron. Avoid ondansetron in patients with congenital long QT syndrome. Ondansetron should be administered with caution to patients who have or may develop prolongation of QTc, including patients with electrolyte abnormalities, congestive heart failure, bradyarrhythmia or patients taking other medicinal products that lead to QT prolongation or electrolyte abnormalities.
Cases of myocardial ischemia have been reported in patients treated with ondansetron. In some patients, especially in the case of intravenous administration, symptoms appeared immediately after administration of ondansetron. Patients should be alerted to the signs and symptoms of myocardial ischaemia.
Hypokalaemia and hypomagnesaemia should be corrected prior to ondansetron administration.
There have been post-marketing reports describing patients with serotonin syndrome (including altered mental status, autonomic

instability and neuromuscular abnormalities) following the concomitant use of ondansetron and other serotonergic drugs (including selective serotonin reuptake inhibitors (SSRI) and serotonin noradrenaline reuptake inhibitors (SNRIs)). If concomitant treatment with ondansetron and other serotonergic drugs is clinically warranted, appropriate observation of the patient is advised.
As ondansetron is known to increase large bowel transit time, patients with signs of subacute intestinal obstruction should be monitored following administration.
In patients with adenotonsillar surgery prevention of nausea and vomiting with ondansetron may mask occult bleeding. Therefore, such patients should be followed carefully after ondansetron. Ondansetron orodispersible tablets formulation contains aspartame and therefore should be taken with caution in patients with phenylketonuria.

Paediatric Population:
Paediatric patients receiving ondansetron with hepatotoxic chemotherapeutic agents should be monitored closely for impaired hepatic function.
CINV: When calculating the dose on a mg/kg basis and administering three doses at 4-hour intervals, the total daily dose will be higher than if one single dose of 5 mg/m2 followed by an oral dose is given. The comparative efficacy of these two different dosing regimens has not been investigated in clinical trials. Cross-trial comparison indicates similar efficacy for both regimens (see section 5.1)

4.5. Interaction with other medicinal products and other forms of Interaction.

There is no evidence that ondansetron either induces or inhibits the metabolism of other drugs commonly co-administered with it. Specific studies have shown that there are no interactions when ondansetron is administered with alcohol, temazepam, furosemide, alfentanil, tramadol, morphine, lidocaine, thiopental or propofol.
Ondansetron is metabolised by multiple hepatic cytochrome P-450 enzymes: CYP3A4, CYP2D6 and CYP1A2. Due to the multiplicity of metabolic enzymes capable of metabolising ondansetron, enzyme inhibition or reduced activity of one enzyme (e.g. CYP2D6 genetic deficiency) is normally compensated by other enzymes and should result in little or no significant change in overall ondansetron clearance or dose requirement.
Caution should be exercised when ondansetron is co-administered with drugs that prolong the QT interval and/or cause electrolyte abnormalities. (See section 4.4)

Use of ondansetron with QT prolonging drugs may result in additional QT prolongation. Concomitant use of ondansetron with cardiotoxic drugs (e.g. anthracyclines (such as doxorubicin, daunorubicin) or trastuzumab), antibiotics (such as erythromycin), antifungals (such as ketoconazole), antiarrhythmics (such as amiodarone) and beta blockers (such as atenolol or timolol) may increase the risk of arrhythmias. (See section 4.4).

Serotonergic Drugs (e.g. SSRIs and SNRIs): There have been post-marketing reports describing patients with serotonin syndrome (including altered mental status, autonomic instability and neuromuscular abnormalities) following the concomitant use of ondansetron and other serotonergic drugs (including SSRIs and SNRIs). (See section 4.4)

Apomorphine: Based on reports of profound hypotension and loss of consciousness when ondansetron was administered with apomorphine hydrochloride, concomitant use with apomorphine is contraindicated.

Phenytoin, Carbamazepine and Rifampicin: In patients treated with potent inducers of CYP3A4 (i.e. phenytoin, carbamazepine, and rifampicin), the oral clearance of ondansetron was increased and ondansetron blood concentrations were decreased.

Tramadol: Data from small studies indicate that ondansetron may reduce the analgesic effect of tramadol

4.6. Fertility, Pregnancy and breastfeeding.

Women of childbearing potential

Women of childbearing potential should consider the use of contraception.

Pregnancy

Based on human experience from epidemiological studies, ondansetron is suspected to cause orofacial malformations when administered during the first trimester of pregnancy.

In one cohort study including 1.8 million pregnancies, first trimester ondansetron use was associated with an increased risk of oral clefts (3 additional cases per 10 000 women treated; adjusted relative risk, 1.24, (95% CI 1.03-1.48)).

The available epidemiological studies on cardiac malformations show conflicting results.

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

Ondansetron should not be used during the first trimester of pregnancy.

Breast-feeding

Tests have shown that ondansetron passes into the milk of lactating animals. It is therefore recommended that mothers receiving ondansetron should not breast-feed their babies.

Fertility

There is no information on the effects of ondansetron on human fertility

4.7. Effects on ability to drive and use machines

In psychomotor testing ondansetron does not impair performance nor cause sedation.
No detrimental effects on such activities are predicted from the pharmacology of ondansetron.

4.8. Undesirable effects

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000) and very rare (<1/10,000) and not known (cannot be estimated from the available data). Very common, common and uncommon events were generally determined from clinical trial data. The incidence in placebo was taken into account. Rare and very rare and not known events were generally determined from post-marketing spontaneous data.
The following frequencies are estimated at the standard recommended doses of ondansetron. The adverse event profiles in children and adolescents were comparable to that seen in adults.

Immune system disorders
Rare: Immediate hypersensitivity reactions sometimes severe, including anaphylaxis.

Nervous system disorders
Very common: Headache.
Uncommon: Seizures, movement disorders (including extrapyramidal reactions such as dystonic reactions, oculogyric crisis and dyskinesia).
Rare: Dizziness predominantly during rapid IV administration.

Eye disorders
Rare: Transient visual disturbances (e.g. blurred vision) predominantly during IV administration.
Very rare: Transient blindness predominantly during IV administration.

Cardiac disorders
Uncommon: Arrhythmias, chest pain with or without ST segment depression, bradycardia.
Rare: QTc prolongation (including Torsade de Pointes).
Not known: Myocardial ischemia* (see section 4.4)

Vascular disorders
Common: Sensation of warmth or flushing.
Uncommon: Hypotension.

Respiratory, thoracic and mediastinal disorders
Uncommon: Hiccups.

Gastrointestinal disorders
Common: Constipation.

Hepatobiliary disorders
Uncommon: Asymptomatic increases in liver function tests.(3)
1. Observed without definitive evidence of persistent clinical sequelae
2. The majority of the blindness cases reported resolved within 20 minutes. Most patients had received chemotherapeutic agents, which included cisplatin. Some cases of transient blindness were reported as cortical in origin.
3. These events were observed commonly in patients receiving chemotherapy with cisplatin.

*These types of adverse drug reactions have been derived from post-marketing experience with Ondansetron via spontaneous case reports and literature cases. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency which is therefore categorized as not known.

Reporting of Suspected Adverse Reactions:

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Pharmacy and Poisons Board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9. Overdose

Symptoms and Signs
There is limited experience of ondansetron overdose. In the majority of cases, symptoms were similar to those already reported in patients receiving recommended doses (see section 4.8). Manifestations that have been reported include visual disturbances, severe constipation,

hypotension and a vasovagal episode with transient second-degree AV block.
Ondansetron prolongs the QT interval in a dose-dependent fashion. ECG monitoring is recommended in cases of overdose.

Paediatric population
Paediatric cases consistent with serotonin syndrome have been reported after inadvertent oral overdoses of ondansetron (exceeded estimated ingestion of 4 mg/kg) in infants and children aged 12 months to 2 years.

Treatment
There is no specific antidote for ondansetron, therefore in all cases of suspected overdose, symptomatic and supportive therapy should be given as appropriate. Further management should be as clinically indicated or as recommended by the national poisons centre, where available.
The use of ipecacuanha to treat overdose with ondansetron is not recommended, as patients are unlikely to respond due to the anti-emetic action of ondansetron itself

5. Pharmacological Properties

5.1. Pharmacodynamic Properties

Pharmacotherapeutic group: Antiemetics and antinauseants, Serotonin (5-HT3) antagonists
ATC code: A04AA01

Mechanism of Action
Ondansetron is a potent, highly selective 5HT3 receptor-antagonist. Its precise mode of action in the control of nausea and vomiting is not known. Chemotherapeutic agents and radiotherapy may cause release of 5HT in the small intestine initiating a vomiting reflex by activating vagal afferents via 5HT3 receptors. Ondansetron blocks the initiation of this reflex. Activation of vagal afferents may also cause a release of 5HT in the area postrema, located on the floor of the fourth ventricle, and this may also promote emesis through a central mechanism. Thus, the effect of ondansetron in the management of the nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy is probably due to antagonism of 5HT3 receptors on neurons located both in the peripheral and central nervous system.
The mechanisms of action in post-operative nausea and vomiting are not known but there may be common pathways with cytotoxic induced nausea and vomiting.
Ondansetron does not alter plasma prolactin concentrations.
The role of ondansetron in opiate-induced emesis is not yet established.

QT Prolongation

The effect of ondansetron on the QTc interval was evaluated in a double blind, randomized, placebo and positive (moxifloxacin) controlled, crossover study in 58 healthy adult men and women. Ondansetron doses included 8 mg and 32 mg infused intravenously over 15 minutes. At the highest tested dose of 32 mg, the maximum mean (upper limit of 90% CI) difference in QTcF from placebo after baseline-correction was 19.6 (21.5) msec. At the lower tested dose of 8 mg, the maximum mean (upper limit of 90% CI) difference in QTcF from placebo after baseline-correction was 5.8 (7.8) msec. In this study, there were no QTcF measurements greater than 480 msec and no QTcF prolongation was greater than 60 msec.

Paediatric population:

CINV

The efficacy of ondansetron in the control of emesis and nausea induced by cancer chemotherapy was assessed in a double-blind randomised trial in 415 patients aged 1 to 18 years (S3AB3006). On the days of chemotherapy, patients received either ondansetron 5 mg/m2 intravenous and ondansetron 4 mg orally after 8 to 12 hours or ondansetron 0.45 mg/kg intravenous and placebo orally after 8 to 12 hours. Post-chemotherapy both groups received 4 mg ondansetron syrup twice daily for 3 days.

Complete control of emesis on worst day of chemotherapy was 49% (5 mg/m2 intravenous and ondansetron 4 mg orally) and 41% (0.45 mg/kg intravenous and placebo orally). Post-chemotherapy both groups received 4 mg ondansetron syrup twice daily for 3 days. There was no difference in the overall incidence or nature of adverse events between the two treatment groups.

A double-blind randomised placebo-controlled trial (S3AB4003) in 438 patients aged 1 to 17 years demonstrated complete control of emesis on worst day of chemotherapy in:

• 73% of patients when ondansetron was administered intravenously at a dose of 5 mg/m2 intravenous together with 2 to 4 mg dexamethasone orally.

• 71% of patients when ondansetron was administered as syrup at a dose of 8 mg together with 2 to 4 mg dexamethasone orally on the days of chemotherapy.

Post-chemotherapy both groups received 4 mg ondansetron syrup twice daily for 2 days. There was no difference in the overall incidence or nature of adverse events between the two treatment groups.

The efficacy of ondansetron in 75 children aged 6 to 48 months was investigated in an open-label, non-comparative, single-arm study (S3A40320). All children received three 0.15 mg/kg doses of intravenous ondansetron, administered 30 minutes before the start of chemotherapy

and then at 4 and 8 hours after the first dose. Complete control of emesis was achieved in 56% of patients.
Another open-label, non-comparative, single-arm study (S3A239) investigated the efficacy of one intravenous dose of 0.15 mg/kg ondansetron followed by two oral ondansetron doses of 4 mg for children aged < 12 years and 8 mg for children aged ≥ 12 years (total no. of children n= 28). Complete control of emesis was achieved in 42% of patients.

5.2. Pharmacokinetic Properties

Following oral administration of ondansetron, absorption is rapid with maximum peak plasma concentrations of about 30 ng/mL being attained and achieved in approximately 1.5 hours after an 8 mg dose. The syrup and tablet formulations are bioequivalent and have an absolute oral bioavailability of 60%. The disposition of ondansetron following oral, intravenous and intramuscular dosing is similar with a terminal elimination half-life of approximately 3 hours and a steady-state volume of distribution of about 140 L. Ondansetron is not highly protein bound (70-76%) and is cleared from the systemic circulation predominantly by hepatic metabolism through multiple enzymatic pathways. Less than 5% of the absorbed dose is excreted unchanged in the urine. The absence of the enzyme CYP2D6 (the debrisoquine polymorphism) has no effect on the pharmacokinetics of ondansetron. The pharmacokinetic properties of ondansetron are unchanged on repeat dosing.
Special Patient Populations:

Gender
Gender differences were shown in the disposition of ondansetron, with females having a greater rate and extent of absorption following an oral dose and reduced systemic clearance and volume of distribution (adjusted for weight).

Children and Adolescents (aged 1 month to 17 years)
In paediatric patients aged 1 to 4 months (n=19) undergoing surgery, weight
normalised clearance was approximately 30% slower than in patients aged 5 to 24 months (n=22) but comparable to the patients aged 3 to 12 years. The half-life in the patient population aged 1 to 4 month was reported to average 6.7 hours compared to 2.9 hours for patients in the 5 to 24 month and 3-to-12-year age range. The differences in pharmacokinetic parameters in the 1-to-4-month patient population can be explained in part by the higher percentage of total body water in neonates and infants

and a higher volume of distribution for water soluble drugs like ondansetron.
In paediatric patients aged 3 to 12 years undergoing elective surgery with general anaesthesia, the absolute values for both the clearance and volume of distribution of ondansetron were reduced in comparison to values with adult patients. Both parameters increased in a linear fashion with weight and by 12 years of age, the values were approaching those of young adults. When clearance and volume of distribution values were normalised by body weight, the values for these parameters were similar between the different age group populations. Use of weight-based dosing compensates for age-related changes and is effective in normalising systemic exposure in paediatric patients.
Population pharmacokinetic analysis was performed on 428 subjects (cancer patients, surgery patients and healthy volunteers) aged 1 month to 44 years following intravenous administration of ondansetron. Based on this analysis, systemic exposure (AUC) of ondansetron following oral or IV dosing in children and adolescents was comparable to adults, with the exception of infants aged 1 to 4 months. Volume was related to age and was lower in adults than in infants and children. Clearance was related to weight but not to age with the exception of infants aged 1 to 4 months. It is difficult to conclude whether there was an additional reduction in clearance related to age in infants 1 to 4 months or simply inherent variability due to the low number of subjects studied in this age group. Since patients less than 6 months of age will only receive a single dose in PONV a decreased clearance is not likely to be clinically relevant.

Elderly
Early Phase I studies in healthy elderly volunteers showed a slight age-related decrease in clearance, and an increase in half-life of ondansetron. However, wide inter-subject variability resulted in considerable overlap in pharmacokinetic parameters between young (< 65 years of age) and elderly subjects (≥ 65 years of age) and there were no overall differences in safety or efficacy observed between young and elderly cancer patients enrolled in CINV clinical trials to support a different dosing recommendation for the elderly.
Based on more recent ondansetron plasma concentrations and exposure-response modelling, a greater effect on QTcF is predicted in patients ≥75 years of age compared to young adults. Specific dosing information is provided for patients over 65 years of age and over 75 years of age for intravenous dosing.

Renal impairment

In patients with renal impairment (creatinine clearance 15-60 mL/min), systemic clearance and volume of distribution are reduced, resulting in a slight, but clinically insignificant increase in elimination half-life (5.4 hours). A study in patients with severe renal impairment who required regular haemodialysis (studied between dialyses) showed ondansetron's pharmacokinetics to be essentially unchanged.

Hepatic impairment
In patients with severe hepatic impairment, systemic clearance is markedly reduced with prolonged elimination half-lives (15-32 hours) and an oral bioavailability approaching 100% because of reduced pre-systemic metabolism.

5.3. Preclinical safety data
No additional data of relevance.

6. Pharmaceutical Particulars
6.1. List of Excipients
Purified Talc
Crosspovidone
Microcrystalline Cellulose
Aspartame
Colloidal Silicon Dioxide
Magnesium stearate
Kyron T-314
Pre-gelatinized Starch
Dry Pineapple flavor

6.2. Incompatibilities
Not Applicable

6.3. Shelf-life
36 months

6.4. Special Precautions for Storage

Store in a dry place, below 30°C. Protect from light.

6.5. Nature and contents of container

1x10 Alu-Alu Pack

6.6. Special precautions for disposal and other handling

No special requirements for disposal.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder

Pharmaken Limited

P.O. Box 95625, Mombasa- Kenya

Manufactured by:
Relax Biotech Pvt. Ltd
862/1, G.I.D.C. Makarpura;
City - Baroda. 390 010. Dist. – Vadodara;
Gujarat State, India

8. Marketing Authorization Number

H2024/CTD10870/24596

9. Date of First Authorization

16th February 2024

10. Date of Revision of the text

November 2024