PROPOSED PROFESSIONAL INFORMATION

SCHEDULING STATUS:

S5

1. NAME OF THE MEDICINE

PAROXETINE UNICORN 20 mg tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

PAROXETINE UNICORN 20: Each tablet contains paroxetine hydrochloride equivalent to 20 mg paroxetine.

PAROXETINE UNICORN 20

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

PAROXETINE UNICORN 20:

White to off-white, round, coated, bi-convex tablets, diameter 10 mm, scored on both walls and sides, marked “P” on one wall and “20” on the other wall, OR white, round, coated, biconvex tablets, with 10 mm diameter, scored on one face and marked "P20" on the other.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

- Depression
- Obsessive Compulsive Disorder (OCD)
- Social phobia
- Panic disorder
- Generalised Anxiety Disorder (GAD)

4.2 Posology and method of administration

Posology

Depression: 20 mg daily. This dose can be increased gradually if needed by 10 mg increments to a maximum of 50 mg daily according to the patient's response.

Panic Disorder: The recommended dose is 40 mg daily. The initial starting dose is 10 mg daily, which may be increased by 10 mg increments. The maximum dose is 60 mg daily.
The low initial starting dose is recommended to minimise the potential worsening of panic symptoms when initiating treatment with **PAROXETINE UNICORN 20**.

Obsessive Compulsive Disorder: The recommended dose is 40 mg daily. The initial starting dose is 20 mg daily, which may be increased by 10 mg increments to a maximum of 60 mg daily.

Social Phobia: The recommended daily dose is 20 mg. This dose may be increased gradually if needed by 10 mg increments to a maximum of 40 mg according to the patient's response.

Generalised Anxiety Disorder: The recommended dose is 20 mg daily. Some patients not responding to a 20 mg dose may benefit from having dose increments of 10 mg of at least one week to a maximum of 50 mg per day according to the patient's response.

Discontinuation of PAROXETINE UNICORN 20: Abrupt discontinuation of **PAROXETINE UNICORN 20** should be avoided (see sections 4.4, 4.8). The taper phase regimen involves an increment decrease in the daily dose by 10 mg/day at weekly intervals. When a daily dose of 20 mg/day is reached, patients should continue on this dose for one week before stopping treatment. If intolerable symptoms occur after a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. The general practitioner may continue decreasing the dose, but at a more gradual rate.

Special populations

Elderly: Elderly subjects may experience increased plasma concentrations with **PAROXETINE UNICORN 20**. Dosing should commence at the adult starting dose and may be increased gradually by 10 mg increments up to 40 mg daily.

Hepatic and renal impairment: Increased plasma concentrations of **PAROXETINE UNICORN 20** may occur in patients with severe renal impairment (creatinine clearance < 30 ml/min) or severe hepatic impairment. The dosage should therefore be restricted to the lower end of the dosage range. Patients should be treated for a sufficient period to ensure that they remain free from symptoms. This may be several months or longer.

Paediatric population

Children: The safety and efficacy of **PAROXETINE UNICORN 20** in children under the age of 18 years have not been established (see section 4.3).

PAROXETINE UNICORN 20 should not be used in the treatment of children and adolescents under the age of 18 years. Suicide-related behaviours (suicide attempts and suicidal thoughts), and hostility (predominantly aggression, oppositional behaviour and anger) were more frequently observed in clinical trials among children and adolescents treated with antidepressants compared to those treated with placebo. If, based on clinical need, a decision to treat is taken, the patient should be carefully monitored for the appearance of suicidal symptoms (see section 4.4).

Method of administration

It is recommended that **PAROXETINE UNICORN 20** be administered as a single dose in the morning with food.

PAROXETINE UNICORN 20 should be swallowed rather than chewed.

4.3 Contraindications

- Hypersensitivity to paroxetine or any of the ingredients of **PAROXETINE UNICORN 20**.
- Concomitant use with serotonin precursors (see sections 4.4, 4.5).
- **MAO Inhibitors: PAROXETINE UNICORN 20** should not be used in combination with MAO inhibitors or within 2 weeks of terminating treatment with MAO inhibitors. MAO inhibitors should not be introduced within 2 weeks of cessation of therapy with **PAROXETINE UNICORN 20**.
- Children under the age of 18 years (see section 4.4).
- Patients with epilepsy, seizures or a history of epilepsy.
- **PAROXETINE UNICORN 20** should not be used in combination with pimozide (see section 4.5).
- Porphyria. **PAROXETINE UNICORN 20** is considered to be unsafe in patients with porphyria.

4.4 Special warnings and precautions for use

Safety and efficacy in children under 18 years have not been established (see section 4.3).

Children and Adolescents under 18 years of age – clinical worsening and suicide risk:

PAROXETINE UNICORN 20 increase the risk compared to placebo of suicidal thinking and behaviour (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders.

Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older.

Long-term safety data in children and adolescents concerning growth, maturation and cognitive and behavioural development are lacking.

PAROXETINE UNICORN 20 is not approved for use in paediatric patients (see sections 4.3, 4.8).

Suicidal thoughts / suicide and psychiatric disorders

Patients with major depressive disorder, both adults and children, may experience worsening of their depression and/or the emergence of suicidal ideation and behaviour, whether or not they are taking antidepressant medicines. This risk may persist until significant remission occurs. A causal role, however, for antidepressant medicines in inducing such behaviour has not been established. Patients being treated with **PAROXETINE UNICORN 20** should, nevertheless, be observed closely for clinical worsening and suicidality, especially at the beginning of a course of therapy, or at any time of dose changes, either increases or decreases.

Because of the possibility of co-morbidity between major depressive disorder and other psychiatric and non-psychiatric disorders, the same precautions observed when treating patients with major depressive disorder should be observed when treating patients with other psychiatric and non-psychiatric disorders.

The following symptoms have been reported in patients being treated with antidepressants, such as **PAROXETINE UNICORN 20**, for major depressive disorder as well as for other indications, both psychiatric and non-psychiatric: anxiety, agitation, panic attacks, insomnia, irritability, hostility (aggressiveness, impulsivity, akathisia, hypomania, and mania). Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, consideration should be given to changing the therapeutic regimen, including possibly discontinuing **PAROXETINE UNICORN 20**, in patients for whom such symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.

Discontinuation of PAROXETINE UNICORN 20 treatment

If the decision is made to discontinue treatment, **PAROXETINE UNICORN 20** should be tapered (see section 4.2).

Abrupt discontinuation of **PAROXETINE UNICORN 20** can lead to withdrawal symptoms such as dizziness, sensory disturbances (including paraesthesia, electric shock sensations and tinnitus), sleep disturbances, insomnia, tremor, confusion, agitation or anxiety, headache, palpitations, emotional instability, irritability, nervousness, vertigo, visual disturbances, nausea and sweating. In the majority of these patients, symptoms are mild to moderate and are self-limiting. No particular patient group appears to be a higher risk of these symptoms; it is therefore advised that when **PAROXETINE UNICORN 20** treatment is no longer required, gradual discontinuation by dose tapering be carried out (see section 4.2).

Patients with epilepsy:

PAROXETINE UNICORN 20 should be used with caution in patients with epilepsy or a history of epilepsy. **PAROXETINE UNICORN 20** should be avoided in patients where epilepsy is poorly controlled (see sections 4.3, 4.4).

Akathisia:

The use of **PAROXETINE UNICORN 20** has been associated with the development of akathisia, which is characterised by an inner sense of restlessness and psychomotor agitation such as an inability to sit or stand still usually associated with subjective distress. This is most likely to occur within the first few weeks of treatment.

Serotonin Syndrome/Neuroleptic Malignant Syndrome:

Development of a serotonin syndrome or neuroleptic malignant syndrome-like events may occur in association with treatment of **PAROXETINE UNICORN 20**, particularly when given in combination with other serotonergic and/or neuroleptic medicines. As these syndromes may result in potentially life-threatening conditions, treatment with **PAROXETINE UNICORN 20** should be discontinued if such events (characterised by clusters of symptoms such as hyperthermia, rigidity, myoclonus and autonomic instability with possible rapid fluctuations of vital signs, mental status changes including confusion, irritability, extreme agitation progressing to delirium and coma) occur. Supportive symptomatic treatment should be initiated.

PAROXETINE UNICORN 20 should not be used in combination with serotonin-precursors (such as L-tryptophan, oxitriptan) due to the risk of serotonergic syndrome (see sections 4.3, 4.5).

Mania and Bipolar disorder:

A major depressive episode may be the initial presentation of bipolar-disorder. It is generally believed (though not established in controlled trials) that treating such an episode with an antidepressant e.g., **PAROXETINE UNICORN 20** alone, can increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. Prior to initiating treatment with **PAROXETINE UNICORN 20**, patients should be adequately screened to determine whether they are at risk for bipolar disorder. Such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder and depression.

It should be noted that **PAROXETINE UNICORN 20** is not approved for use in treating bipolar depression.

PAROXETINE UNICORN 20 should be used with caution in patients with a history of mania.

Haemorrhage:

SSRIs/SNRI's may increase the risk of postpartum haemorrhage, and this risk could potentially apply also to **PAROXETINE UNICORN 20** (see sections 4.6, 4.8).

Patients concomitantly treated with **PAROXETINE UNICORN 20** and anticoagulant medicines have an increased risk for bleeding, or patients with a known tendency or with predisposing conditions for bleeding, may have an increased tendency of skin and mucous membrane bleedings.

Co-administration of **PAROXETINE UNICORN 20** with warfarin may result in increased bleeding in the presence of unaltered prothrombin times.

The elderly and patients at high risk of gastrointestinal bleeding should be cautioned against the use of **PAROXETINE UNICORN 20** with NSAIDs, due to the increased risk of upper gastrointestinal bleeding.

Haemorrhagic manifestations e.g., gastrointestinal haemorrhage has been reported in patients taking SSRIs concomitantly with NSAID's. Caution is advised in the elderly and patients with a history of bleeding disorders or conditions which may predispose to bleeding (see section 4.5).

Risperidone:

Co-administration with risperidone may lead to increased toxicity (see section 4.5).

Alcohol

The concomitant use of **PAROXETINE UNICORN 20** and alcohol is not advised.

Increased risk for bone fractures:

Epidemiological studies, mainly conducted in patients 50 years of age and older, show an increased risk of bone fractures in patients receiving SSRIs and tricyclic antidepressants (TCAs) (see section 4.8).

Cardiac Condition:

Administration of **PAROXETINE UNICORN 20** to patients with a serious cardiovascular disorder such as (unstable) angina pectoris, poorly monitored cardiac decompensation, ventricular rhythm disorder and acute myocardial infarction, has not been studied and must therefore be avoided. If antidepressant medication is nevertheless indicated for such patients, **PAROXETINE UNICORN 20** should be administered with caution.

Seizures:

Seizures may occur in patients treated with **PAROXETINE UNICORN 20**.

PAROXETINE UNICORN 20 should be discontinued in any patient who develops seizures or when there is an increase in seizure frequency (see sections 4.3, 4.4).

Electro-Convulsive Therapy (ECT):

Clinical experience of the concurrent administration of **PAROXETINE UNICORN 20** and electro-convulsive therapy is lacking.

Hyponatraemia:

Hyponatraemia, which is generally reversible on discontinuation of **PAROXETINE UNICORN 20**, may occur predominantly in the elderly.

Glaucoma:

PAROXETINE UNICORN 20 may cause mydriasis and should be used with caution in patients with narrow angle glaucoma.

Diabetes mellitus:

PAROXETINE UNICORN 20 may alter glycaemic control and therefore caution should be used in patients with diabetes mellitus. Insulin and/or oral hypoglycaemic dosage may need to be adjusted.

4.5 Interaction with other medicines and other forms of interaction

- Interaction between **PAROXETINE UNICORN 20** and serotogenic medicines (e.g., monoamine oxidase (MAO) inhibitors (see section 4.3) and also between **PAROXETINE UNICORN 20** L-tryptophan, triptans, tramadol, linezolid, methylthioninium chloride (methylene blue), SSRI's, pethidine and St. John's Wort (*hypericum perforatum*) may occur, resulting in a "serotonin syndrome". The risk of using **PAROXETINE UNICORN 20** in combination with other CNS active

medicines has not been systematically evaluated. Consequently, caution is advised if concomitant administration is required.

- Co-administration of **PAROXETINE UNICORN 20** with anti-convulsants may be associated with an increased incidence of adverse events.
- **PAROXETINE UNICORN 20** inhibits the specific hepatic cytochrome P450 isozyme CYP2D6 responsible for the metabolism of debrisoquine and sparteine. This may lead to enhanced plasma levels of those co-administered medicines which are metabolised by this isoenzyme. Medicine metabolised by this isozyme include certain tricyclic antidepressants (e.g., nortriptyline, amitriptyline, imipramine and desipramine), phenothiazine neuroleptics (e.g., perphenazine) risperidone, Type 1c antidysrhythmics (e.g., propafenone) and metoprolol.
- Co-administration with risperidone may lead to increased toxicity thereof.
- Caution is also advised with fentanyl used in general anaesthesia or tramadol in the treatment of chronic pain.
- Concurrent administration of **PAROXETINE UNICORN 20** and lithium should be undertaken with caution. Lithium levels should be monitored.
- Co-administration of **PAROXETINE UNICORN 20** and phenytoin is associated with decreased plasma concentrations of paroxetine and increased adverse experiences (diarrhoea, indifference, imbalance, nervousness, ataxia and vertigo). No initial dosage adjustment of **PAROXETINE UNICORN 20** is considered necessary when these medicines are co-administered. Any subsequent adjustments should be guided by clinical effect.
- Primidone is partially metabolised to phenobarbitone, which induces many cytochrome P450 enzymes. Administration with any of these medicines concomitantly with **PAROXETINE UNICORN 20** may reduce the systemic availability of paroxetine. No initial dosage adjustments of

PAROXETINE UNICORN 20 are recommended, but subsequent titration should be based on clinical effects.

- Concomitant administration of pimozide with **PAROXETINE UNICORN 20** may increase the systemic availability of pimozide. Due to the narrow therapeutic index of pimozide and its known ability to prolong the QT interval, concomitant use of pimozide and **PAROXETINE UNICORN 20** is contra-indicated (see section 4.3).
- Daily administration of **PAROXETINE UNICORN 20** may significantly increase the plasma levels of procyclidine; other anti-cholinergic medicines may be similarly affected. If anti-cholinergic effects are seen, the dose of procyclidine should be reduced.
- **PAROXETINE UNICORN 20** should be administered with great caution to patients receiving oral anticoagulants (see section 4.4), aspirin or nonsteroidal medicines (NSAIDs).
- Sumatriptan may increase the risk of adverse reactions when used in combination with **PAROXETINE UNICORN 20**. If concomitant therapy is clinically warranted, appropriate observation of the patient is advised.
- Elevated theophylline concentrations may occur after concurrent use of **PAROXETINE UNICORN 20**. Monitoring of theophylline serum concentrations during concurrent use is recommended.
- Reduced efficacy of tamoxifen has been reported with concomitant usage of some SSRI antidepressants. As a reduced effect of tamoxifen cannot be excluded, co-administration with potent CYP2D6 inhibitors (including **PAROXETINE UNICORN 20**) should whenever possible be avoided.
- The absorption and pharmacokinetics of **PAROXETINE UNICORN 20** are not affected, or only marginally affected by food, antacids propranolol.
- Concurrent administration of **PAROXETINE UNICORN 20** with digoxin should be undertaken with caution.

- When **PAROXETINE UNICORN 20** is to be co-administered with a known medicine metabolising enzyme inhibitor, such as cimetidine, consideration should be given to using doses at the lower end of the range. No initial dosage adjustment of **PAROXETINE UNICORN 20** is considered necessary when it is to be co-administered with known medicine metabolising enzyme inducers. Any subsequent dosage adjustment should be guided by clinical effects (tolerability and efficacy).

4.6 Fertility, pregnancy and lactation

The safety of **PAROXETINE UNICORN 20** in pregnancy or lactation has not been established.

Patients should be advised to notify their medical practitioner if they become pregnant or intend to become pregnant during therapy.

Observational data indicate an increased risk (less than 2-fold) of postpartum haemorrhage following SSRI/SNRI exposure within the month prior to birth (see sections 4.4, 4.8).

Teratogenic effects:

Epidemiological studies suggest an increased risk of congenital malformations, particularly cardiovascular (e.g., ventricular and atrial septum defects), associated with the use of **PAROXETINE UNICORN 20** during the first trimester. The mechanism is unknown. **PAROXETINE UNICORN 20** should only be used during pregnancy when strictly indicated. If a patient becomes pregnant while taking **PAROXETINE UNICORN 20**, she should be advised of the potential harm to the foetus. Unless the benefits of paroxetine to the mother justify continuing treatment, consideration should be given to either discontinuing **PAROXETINE UNICORN 20** therapy or switching to another antidepressant (see section 4.4: ***Discontinuation of PAROXETINE UNICORN 20 treatment***). For women who intend to become pregnant or are in their first trimester of pregnancy, **PAROXETINE UNICORN 20** should only be initiated after consideration of the other available treatment options.

Non-teratogenic effects:

Neonates must be observed if maternal use of **PAROXETINE UNICORN 20** continues into the later stages of pregnancy, particularly the third trimester. The following symptoms may occur in the neonate after maternal **PAROXETINE UNICORN 20** use in later stages of pregnancy: respiratory distress, cyanosis, apnoea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycaemia, hypertonia, hypotonia, hyperreflexia, tremor, jitteriness, irritability, lethargy, constant crying, somnolence and difficulty in sleeping. These symptoms could be due to either serotonergic effects or withdrawal symptoms. In a majority of instances, the complications begin immediately or soon (<24 hours) after delivery (see section 4.4).

Infants exposed to SSRIs in pregnancy may have an increased risk for persistent pulmonary hypertension of the new-born (PPHN).

PAROXETINE UNICORN 20 should only be used during pregnancy when strictly indicated. The prescribing physician will need to weigh the option of alternative treatments in women who are pregnant or are planning to become pregnant. Abrupt discontinuation should be avoided during pregnancy (see section 4.4: ***Discontinuation of PAROXETINE UNICORN 20 treatment***).

4.7 Effects on ability to drive and use machines

Patients should be cautioned about their ability to drive a car and operate machinery.

4.8 Undesirable effects

System Organ Class	**Frequency**	**Side effects**

System Organ Class	Frequency	Side effects
Blood and lymphatic system disorders	Less frequent	Abnormal bleeding, predominantly of the skin and mucous membranes (mostly ecchymosis, but also in the gastrointestinal tract, central nervous system and eye) purpura, bruising, thrombocytopenia.
Endocrine disorders	Less frequent	Syndrome of inappropriate anti-diuretic hormone secretion (SIADH).
Metabolism and nutrition disorders	Frequent	Decreased or increased appetite, anorexia, weight loss, increased risk of gastrointestinal bleeding, hyponatraemia (which may occur predominantly in elderly patients), changes in blood sugar
Psychiatric disorders	Frequent Less frequent	Somnolence, insomnia, agitation Confusion, hallucinations, amnesia, impaired concentration, abnormal dreams, anxiety, in children reports of hostility, suicidal ideation and self-harm, depersonalisation, panic attacks, akathisia, manic reactions, suicidal ideation and suicidal behaviour.
Nervous system disorders	Frequent Less frequent	Dizziness, tremor, drowsiness, headache, fatigue Extrapyramidal disorders, migraine, anxiety, restlessness, nervousness, insomnia, paraesthesia, convulsions, Serotonin syndrome (symptoms may include agitation, confusion, diaphoresis, hallucinations, hyperreflexia, myoclonus, shivering, tachycardia and tremor).
Eye disorders	Less frequent	Blurred or abnormal vision, anisocoria, mydriasis, acute glaucoma.

System Organ Class	**Frequency**	**Side effects**
Cardiac disorders	Less frequent	Palpitations, tachycardia.
Vascular disorders	Less frequent	Postural hypotension, hypertension.
Respiratory, thoracic and mediastinal disorders	Frequent Less frequent	Yawning. Chest pain, difficulty in breathing, sinusitis, bronchitis, coughing, pharyngitis, rhinitis.
Gastrointestinal disorders	Frequent Less frequent	Constipation, diarrhoea, dry mouth, nausea, vomiting, dyspepsia, abdominal pain, flatulence. Increased risk of gastrointestinal bleeding
Hepato-biliary disorders	Less frequent	Elevation of hepatic enzymes, hepatic events (such as hepatitis, sometimes associated with jaundice and/ or liver failure). Discontinuation of **PAROXETINE UNICORN 20** should be considered if there is prolonged elevation of liver function test results.
Skin and subcutaneous tissue disorders	Frequent Less frequent	Excessive sweating. Skin rashes, pruritus, eczema, alopecia, pruritus, erythema multiforme, Stevens Johnson's syndrome, toxic epidermal necrolysis photosensitivity reactions, cutaneous vasculitis.

System Organ Class	Frequency	Side effects
Musculoskeletal, connective tissue and bone disorders	Less frequent	Myalgia, myasthenia, myopathy, arthralgia, increased risk of bone fractures.
Renal and urinary disorders	Less frequent	Urinary retention, urinary tract infection, urinary incontinence.
Reproductive system and breast disorders	Frequent Less frequent Frequency unknown	Sexual dysfunction. Dysmenorrhoea, menstrual disorder, vaginitis, hyperprolactinaemia / galactorrhoea, priapism. Postpartum haemorrhage*. Safety of **PAROXETINE UNICORN 20** in pregnancy has not been established (see section 4.6)
General disorders and administrative site conditions	Less frequent	Peripheral oedema, asthenia, body weight gain.

*This event has been reported for the therapeutic class of SSRIs/SNRIs (see sections 4.4, 4.6).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reactions Reporting

Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

Adverse reactions must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to vigilance@unicornpharma.co.za.

4.9 Overdose

Symptoms of overdose:

Vomiting, dilated pupils, fever, blood pressure changes, headache, involuntary muscle contractions, agitation, anxiety, tachycardia, coma and ECG changes.

Treatment of overdose:

Treatment is symptomatic and supportive.

There is no specific antidote. To decrease absorption, the stomach should be emptied by gastric lavage or induction of emesis or both. This should be followed by administration of 20 to 30 g of activated charcoal every four to six hours during the first 24 hours after ingestion. Frequent monitoring of vital signs and careful observation is recommended.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 1.2 Psycho-analeptics (Antidepressants).

Paroxetine is a selective serotonin (5-hydroxy-tryptamine, (5HT)) re-uptake inhibitor (SSRI). The antidepressant effect of paroxetine is thought to be related to its effect on serotonergic neurotransmission.

Paroxetine is chemically unrelated to the tricyclic or tetracyclic antidepressants.

5.2 Pharmacokinetic properties

Absorption:

After oral administration, paroxetine is readily absorbed from the gastrointestinal tract. Absorption is not influenced by the presence of food, milk or antacids. Steady-state is achieved in 7 to 14 days in most patients.

Distribution:

Paroxetine is highly protein bound (95 %) and undergoes extensive first-pass metabolism in the liver where it is metabolised in part by cytochrome P450 2D6 (CYP2D6).

Metabolism:

The metabolites appear to be clinically inactive.

Elimination:

The elimination half-life is about 24 hours, but there is wide inter-subject variability. Paroxetine is excreted renally (approximately 64 %) and in the faeces (approximately 36 %) mainly as inactive metabolites.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Eudagrit, magnesium stearate, mannitol, microcrystalline cellulose, Opadry AMB White, sodium starch glycollate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 ºC.

Protect from light.

Do not remove blister from the carton until required for use.

6.5 Nature and contents of container

Aluminium blister packs of 30 tablets.

Each blister strip contains 10 tablets.

White cylindrical polypropylene homopolymer tube with a white natural LDPE cap, containing 30 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Unicorn Pharmaceuticals (Pty) Ltd

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Woodstock, Cape Town

8001, South Africa

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8. REGISTRATION NUMBER:

A38/1.2/0072

9. DATE OF FIRST AUTHORISATION

September 2009

10. DATE OF REVISION OF TEXT

01 Aug 2021