PROFESSIONAL INFORMATION FOR

QUETIAPINE 25 / 100 / 200 / 300 UNICORN

SCHEDULING STATUS:

S5

1. NAME OF THE MEDICINE

QUETIAPINE 25 UNICORN film coated tablets

QUETIAPINE 100 UNICORN film coated tablets

QUETIAPINE 200 UNICORN film coated tablets

QUETIAPINE 300 UNICORN film coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

QUETIAPINE 25 UNICORN: Each film coated tablet contains quetiapine fumarate equivalent to 25 mg of quetiapine free base.

QUETIAPINE 100 UNICORN: Each film coated tablet contains quetiapine fumarate equivalent to 100 mg of quetiapine free base.

QUETIAPINE 200 UNICORN: Each film coated tablet contains quetiapine fumarate equivalent to 200 mg of quetiapine free base.

QUETIAPINE 300 UNICORN: Each film coated tablet contains quetiapine fumarate equivalent to 300 mg of quetiapine free base.

Contains sugar:

QUETIAPINE 25 UNICORN contains 10,7 mg lactose monohydrate per tablet

QUETIAPINE 100 UNICORN contains 42,9 mg lactose monohydrate per tablet

QUETIAPINE 200 UNICORN contains 85,7 mg lactose monohydrate per tablet

QUETIAPINE 300 UNICORN contains 128,6 mg lactose monohydrate per tablet

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

QUETIAPINE 25 UNICORN: Peach coloured, round shaped, biconvex, film coated tablets, debossed with “J” on one side and “25” on the other side.

QUETIAPINE 100 UNICORN: Yellow coloured, round shaped, biconvex, film coated tablets, debossed with “J” on one side and “100” on the other side.

QUETIAPINE 200 UNICORN: White coloured, round shaped, biconvex, film coated tablets, debossed with “J” on one side and “200” on other side.

QUETIAPINE 300 UNICORN: White coloured, capsule shaped, film coated tablets, debossed with “J” on one side and “300” on other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

QUETIAPINE UNICORN is indicated for the treatment of schizophrenia.

QUETIAPINE UNICORN is also indicated for the treatment of manic episodes associated with a bipolar disorder. Safety and efficacy beyond 12 weeks have not been demonstrated.

4.2 Posology and method of administration

Adults:

QUETIAPINE UNICORN should be administered orally twice daily as 2 divided doses, with or without food.

For the treatment of schizophrenia, the total daily dose for the first 4 days of therapy is 50 mg (Day 1; 25 mg twice daily), 100 mg (Day 2; 50 mg twice daily), 200 mg (Day 3; 100 mg twice daily) and 300 mg (Day 4; 150 mg twice daily).

From Day 4 onwards, the dose should be adjusted according to the response to a usual dose range of 300 to 450 mg/day although the daily dose may be adjusted in some patients within the range 150 to 750 mg/day, depending on the clinical response and tolerability of the individual patient.

For the treatment of manic episode associated with bipolar disorder, the total daily dose for the first 4 days of therapy Is 100 mg (Day 1; 50 mg twice daily), 200 mg (Day 2; 100 mg twice daily), 300 mg (Day 3; 150 mg twice daily) and 400 mg (Day 4; 200 mg twice daily). Further dosage adjustments up to 800 mg/day by Day 6 should be in increments or no greater than 200 mg/day. The dose may be adjusted depending on the clinical response and tolerability of the individual patient, within the range of 200-800 mg/day. The usual effective dose is in the range of 400-800 mg/day.

Special populations

Elderly:

QUETIAPINE UNICORN treatment should be given with caution in the elderly with reduced initial and target dosages, and slower dosage titrations that may be required in these patients. Elderly patients should be started on **QUETIAPINE UNICORN** 25 mg/day. The dose should be increased daily, in increments of 25 to 50 mg, to an effective dose.

Renal and hepatic impairment:

QUETIAPINE UNICORN should be given with caution and in reduced doses to patients with hepatic and renal impairment as clearance of quetiapine is reduced by approximately 25 % in these patients.

A starting dose of 25 mg/day **QUETIAPINE UNICORN** is recommended to be increased daily in increments of 25 to 50 mg to an effective dose.

4.3 Contraindications

QUETIAPINE UNICORN is contraindicated in the following:

- Hypersensitivity to quetiapine or to any of the inactive ingredients in **QUETIAPINE UNICORN** (see section 6.1).
- Pregnancy and lactation.
- Safety in children and adolescents has not been demonstrated.
- Patients with advanced liver and renal function impairment.
- Concomitant administration of cytochrome P450 3A4 inhibitors, such as HIV protease inhibitors, azole antifungal medicines, erythromycin, clarithromycin and nefazodone, is contraindicated (see section 4.5).

4.4 Special warnings and precautions for use

Suicide/suicidal thoughts or clinical worsening

Depression in bipolar disorder is associated with an increased risk of suicidal thoughts, self-harm and suicide (suicide- related events). This risk persists until significant remission occurs. As improvement may not occur during the first few weeks or more of treatment, therefore patients should be closely

monitored in the interim. It is general clinical experience that the risk of suicide may increase in the early stages of recovery. In addition, healthcare professionals should consider the potential risk of suicide-related events after abrupt cessation of **QUETIAPINE UNICORN** treatment, due to the known risk factors for the disease being treated. Patients with a history of suicide-related events, or those exhibiting a significant degree of suicidal ideation prior to commencement of treatment are known to be at greater risk of suicidal thoughts or suicide attempts, and should receive careful monitoring during treatment. Close supervision of patients and in particular those at high risk should accompany medicine therapy especially in early treatment and following dose changes. Patients (and caregivers of patients) should be alerted about the need to monitor for any clinical worsening, suicidal behaviour or thoughts and unusual changes in behaviour and to seek medical advice immediately if these symptoms present.

Metabolic risk

Given the risk for worsening of their metabolic profile, including changes in weight, blood glucose (see hyperglycaemia) and lipids, patients' metabolic parameters should be assessed at the time of treatment initiation and changes in these parameters should be regularly controlled during the course of treatment (see also section 4.8).

Tardive Dyskinesia and Extrapyramidal symptoms

There is a potential for **QUETIAPINE UNICORN** to cause tardive dyskinesia. In the event of signs and symptoms of tardive dyskinesia appearing, the discontinuation of **QUETIAPINE UNICORN** should be considered.

In placebo-controlled clinical trials of adult patients with schizophrenia and bipolar mania the incidence of extrapyramidal symptoms was no different from that of placebo across the recommended therapeutic dose range. This predicts that **QUETIAPINE UNICORN** has less potential than typical antipsychotic medicines to induce tardive dyskinesia in schizophrenia and bipolar mania patients. In short-term placebo-controlled clinical trials for bipolar depression, the incidence of extrapyramidal symptoms was higher in **QUETIAPINE UNICORN** treated patients than in placebo treated patients.

Somnolence and dizziness

Quetiapine treatment has been associated with somnolence and related symptoms, such as sedation (see section 4.8). Patients experiencing somnolence of severe intensity may require more frequent contact for a minimum of two weeks from onset of somnolence, or until symptoms improve and treatment discontinuation may need to be considered.

Cardiovascular disease

Orthostatic hypotension may occur and is more common in elderly patients than in younger patients, in particular during the initial dose-titration period. Caution should be exercised when **QUETIAPINE UNICORN** is prescribed to patients with known cardiovascular, cerebrovascular or any other disorders

predisposing hypotension particularly in the elderly (these disorders and orthostatic hypotension may be exacerbated).

Precaution should be exercised especially in the elderly when **QUETIAPINE UNICORN** is prescribed concomitantly with medicines known to prolong the QTc interval (see section 4.8).

Sleep apnoea syndrome

QUETIAPINE UNICORN should be used with caution in patients receiving concomitant central nervous system depressants and who have a history of or are at risk for sleep apnoea, such as those who are overweight/ obese or are male.

Seizures

Patients with a history of seizures should be treated with caution.

Neuroleptic Malignant Syndrome

QUETIAPINE UNICORN treatment should be discontinued and appropriate medical treatment given in patients showing the symptoms of neuroleptic malignant syndrome. Clinical manifestations of neuroleptic malignant syndrome include hyperthermia, altered mental status, muscular rigidity, autonomic instability, and increased creatine phosphokinase.

Severe neutropenia and agranulocytosis

Severe neutropenia (neutrophil count $<0.5 \times 10^9$/L), without infection, has been uncommonly reported. There have been reports of agranulocytosis

(severe neutropenia with infection) among all patients treated with quetiapine, as contained in **QUETIAPINE UNICORN**, during clinical trials as well as post-marketing reports. Most cases have occurred within the first two months of starting therapy. There was no apparent dose relationship. Some cases were reported to be fatal. Possible risk factors for neutropenia include pre-existing low white blood cell count (WBC) and history of medicine induced neutropenia. There have been cases of agranulocytosis in patients without pre-existing risk factors. Neutropenia should be considered in patients presenting with infection, particularly in the absence of obvious predisposing factor(s), or in patients with unexplained fever, and should be managed as clinically appropriate.

QUETIAPINE UNICORN should be discontinued in patients with a neutrophil count <1.0 x 10^9/L. Patients should be observed for signs and symptoms of infection and neutrophil counts followed (until they exceed 1.5 x 10^9/L). Patients should be advised to immediately report the appearance of signs/symptoms consistent with agranulocytosis or infection (e.g. fever, weakness, lethargy, or sore throat) at any time during **QUETIAPINE UNICORN**. Such patients should have a WBC count and an absolute neutrophil count (ANC) performed promptly, especially in the absence of predisposing factors.

<u>Anticholinergic (muscarinic) effects</u>

Norquetiapine (an active metabolite of quetiapine) has moderate to strong affinity for several muscarinic receptor subtypes. This enhances adverse

reactions reflecting anticholinergic effects; therefore **QUETIAPINE UNICORN** should be used with caution in patients receiving medications having anticholinergic (muscarinic) effects.

QUETIAPINE UNICORN should be used with caution in patients with a current diagnosis or prior history of urinary retention, clinically significant prostatic hypertrophy, intestinal obstruction or related conditions, increased intraocular pressure or narrow angle glaucoma (see sections 4.5 and 4.8).

Weight

Weight gain has been reported and therefore patients should be monitored and managed as clinically appropriate as in accordance with utilised antipsychotic guidelines (see section 4.8).

Hyperglycaemia

Hyperglycaemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics, including **QUETIAPINE UNICORN**.

Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics such as **QUETIAPINE UNICORN**, should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g. obesity, family history of diabetes) who are starting treatment with atypical antipsychotics, should be monitored for symptoms of hyperglycaemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycaemia during treatment with atypical antipsychotics should undergo

fasting blood glucose testing. Hyperglycaemia may resolve when **QUETIAPINE UNICORN** is discontinued; however, some patients may require continuation of antidiabetic treatment.

Lipids

Increases in triglycerides, LDL and total cholesterol, and decreases in HDL cholesterol have been reported (see section 4.8).

QT prolongation

QT prolongation was reported with quetiapine at therapeutic doses (see section 4.8) and in overdose (see section 4.9). As with other antipsychotics, caution should be used when **QUETIAPINE UNICORN** is prescribed in patients with cardiovascular disease or family history of QT prolongation. Also, caution should be used when **QUETIAPINE UNICORN** is prescribed either with medicines known to increase QT interval or with concomitant neuroleptics, especially in the elderly, in patients with congenital long QT syndrome, congestive heart failure, heart hypertrophy, hypokalaemia or hypomagnesaemia (see section 4.5).

Cardiomyopathy and myocarditis

Cardiomyopathy and myocarditis have been reported with quetiapine in clinical trials and during the post-marketing experience.
Treatment with **QUETIAPINE UNICORN** should be reassessed in patients with suspected cardiomyopathy or myocarditis.

Withdrawal

Acute withdrawal symptoms such as insomnia, nausea, headache, diarrhoea, vomiting, dizziness and irritability have been reported after abrupt cessation of quetiapine. Gradual withdrawal over a period of at least one to two weeks is advisable (see section 4.8).

Elderly patients with dementia-related psychosis

QUETIAPINE UNICORN is not indicated for the treatment of dementia-related psychosis. An increased risk of cerebrovascular adverse events has been reported in the dementia population with some atypical antipsychotics. **QUETIAPINE UNICORN** should be used with caution in patients with risk factors for stroke.

Elderly patients with Parkinson's disease

QUETIAPINE UNICORN should be used cautiously if prescribed to elderly patients with parkinson's disease

Dysphagia

Dysphagia (see section 4.8) has been reported with quetiapine; therefore **QUETIAPINE UNICORN** should be used with caution in patients at risk for aspiration pneumonia.

Constipation and intestinal obstruction

Constipation and intestinal obstruction have been reported with quetiapine (see section 4.8). This includes fatal reports in patients who are at higher risk

of intestinal obstruction, including those that are receiving multiple concomitant medications that decrease intestinal motility and/or may not report symptoms of constipation. Patients with intestinal obstruction/ileus should be monitored closely with urgent care.

Venous thromboembolism (VTE)

Patients treated with antipsychotics often present with acquired risk factors for VTE therefore all possible risk factors for VTE should be identified before and during treatment with **QUETIAPINE UNICORN** and preventive measures should be commenced.

Pancreatitis

Pancreatitis has been reported. Many patients had factors which are known to be associated with pancreatitis such as increased triglycerides, gallstones, and alcohol consumption.

Lactose

QUETIAPINE UNICORN contains lactose.

Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take **QUETIAPINE UNICORN.**

Misuse and abuse

Cases of misuse and abuse have been reported therefore caution must be exercised when prescribing **QUETIAPINE UNICORN** to patients with a history of alcohol or drug abuse.

Paediatric population

QUETIAPINE UNICORN is not recommended for use in children and adolescents below 18 years of age due to a lack of data to support use in this age group.

4.5 Interaction with other medicinal products and other forms of interaction

The central nervous system effects of other centrally acting medicines and alcohol may be enhanced by **QUETIAPINE UNICORN** and should be used with caution.

The antihypertensive effects of antihypertensive medicines may be enhanced by concomitant used with **QUETIAPINE UNICORN.**

QUETIAPINE UNICORN should not be used with inhibitors of the cytochrome P450 3A (CYP3A) enzyme, such as erythromycin, fluconazole, ketoconazole, because the major route of metabolism of quetiapine involves the CYP3A4 isoenzyme (see section 4.3).

Grapefruit juice must be avoided while on **QUETIAPINE UNICORN.**

Quetiapine did not alter the pharmacokinetics of lithium when used concomitantly.

QUETIAPINE UNICORN should be used with caution with inducers of the hepatic cytochrome P450 enzymes, such as carbamazepine, phenytoin, barbiturates, and rifampicin as the metabolism of quetiapine will be increased. This may require an adjustment of the **QUETIAPINE UNICORN** dosage depending of the clinical response. Withdrawing these inducers or replacing them with non-inducer medications (e.g. sodium valproate) may require a reduced dose adjustment of **QUETIAPINE UNICORN.**

The pharmacokinetics of quetiapine was not significantly altered following co-administration with the antipsychotics risperidone or haloperidol. Concomitant use of quetiapine and thioridazine caused increases in the oral clearance of quetiapine.

Caution should be exercised when **QUETIAPINE UNICORN** is used concomitantly with medicines known to cause electrolyte imbalance or to increase QT interval.

False positive results in enzyme immunoassays for methadone and tricyclic antidepressants in patients who have taken quetiapine have been reported. An appropriate chromatographic technique is recommended to confirm questionable immunoassay screening results.

4.6 Fertility, pregnancy and lactation

QUETIAPINE UNICORN is contraindicated during pregnancy as safety has not been demonstrated (see section 4.3).

Animal studies have shown reproductive toxicity.

Breastfeeding

The degree to which quetiapine is excreted into human milk is unknown. Women who are breastfeeding should therefore be advised to avoid breastfeeding while taking **QUETIAPINE UNICORN** (see section 4.3).

Fertility

The effects of **QUETIAPINE UNICORN** on human fertility have not been assessed.

4.7 Effects on ability to drive and use machines

Patients should avoid operating hazardous machines, including motor vehicles, because **QUETIAPINE UNICORN** may cause somnolence which may interfere with activities requiring mental alertness**.**

4.8 Undesirable effects

Summary of adverse reactions

Blood and the lymphatic system disorders:

Frequent: Leucopoenia, decreased haemoglobin, decreased neutrophil count, and eosinophils increased.

Less frequent: Neutropenia, thrombocytopenia, anaemia, platelet count decreased, agranulocytosis.

Immune system disorders:

Less frequent: Hypersensitivity (angioedema, anaphylaxis, urticaria/rash).

Endocrine disorders:

Frequent: Hyperprolactinaemia, serum transaminase (ALT, AST increased), GGT increased, decreases in total T_4 decreases in free T_4, decreases in total T_3, increases in TSH.

Less frequent: Non-fasting serum triglyceride and total cholesterol increased. Decreases in free T_3, hypothyroidism, inappropriate antidiuretic hormone secretion.

Metabolism and nutrition disorders:

Frequent: Elevations in serum triglyceride levels, elevations in total cholesterol (predominantly LDL cholesterol), decreases in HDL cholesterol, weight gain, increased appetite, blood glucose increased to hyperglycaemic levels.

Less frequent: Hyponatraemia, diabetes mellitus, exacerbation of pre-existing diabetes, metabolic syndrome.

Psychiatric disorders:

Frequent: Abnormal dreams and nightmares, suicidal ideation and suicidal behaviour.

Less frequent: Somnambulism and related reactions such as sleep talking and sleep related eating disorder.

Nervous system disorders:

Frequent: Somnolence, dizziness, anxiety, syncope, headache, extrapyramidal symptoms (akathisia, akinesia, cogwheel rigidity, extrapyramidal syndrome, hypertonia, hypokinesia, neck rigidity and tremor), dysarthria.

Less frequent: seizures (see section 4.4), neuroleptic malignant syndrome (see section 4.4), restless legs syndrome, tardive dyskinesia, syncope.

Eye disorders:

Frequent: Blurred vision.

Less frequent: Dry eyes.

Ear and labyrinth disorders:

Less frequent: Ear pain.

Cardiac disorders:

Frequent: Tachycardia, palpitations.

Less frequent: Postural hypotension, hypertension, QT prolongation, bradycardia.

Vascular disorders:

Frequent: Orthostatic hypotension.

Less frequent: Venous thromboembolism.

Frequency unknown: Stroke.

Respiratory, thoracic and mediastinal disorders:

Frequent: Dyspnoea.

Less frequent: Rhinitis, chest pain.

Gastrointestinal disorders:

Frequent: Dyspepsia, dry mouth, constipation, weight gain (particular during early treatment), vomiting.

Less frequent: Diarrhoea, GGT increased abdominal pain, dysphagia, pancreatitis, intestinal obstruction/Ileus.

Hepatobiliary disorders:

Frequent: Elevations in serum alanine aminotransferase (ALT), elevations in GGT levels.

Less frequent: Elevations in serum aspartate aminotransferase (AST), jaundice, hepatitis.

Skin and subcutaneous tissue disorders:

Less frequent: Rash, peripheral oedema, angioedema, Stevens Johnson Syndrome.

Frequency unknown: Toxic Epidermal Necrolysis, erythema multiforme drug rash with eosinophilia and systemic symptoms (DRESS).

Musculoskeletal, connective tissue and bone disorders:

Less frequent: Myalgia, back pain, rhabdomyolysis.

Renal and urinary disorders:

Less frequent: Urinary tract infection, urinary retention.

Reproductive system and breast disorders:

Less frequent: Sexual dysfunction, Priapism, galactorrhoea, breast swelling, menstrual disorder.

General disorders and administration site conditions:

Frequent: Mild asthenia, peripheral oedema, irritability, pyrexia.

Less frequent: hypothermia.

Investigations:

Less frequent: Elevations in blood creatine phosphokinase.

Description of selected adverse reactions

Withdrawal

Acute withdrawal symptoms such as insomnia, nausea, headache, diarrhoea, vomiting, dizziness and irritability have been reported after abrupt cessation of quetiapine. Gradual withdrawal over a period of at least one to two weeks is advisable (see section 4.8).

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

Signs and symptoms are those of the active substance's known pharmacological effects (drowsiness and sedation, tachycardia, hypotension and anticholinergic effects). Overdose could lead to QT prolongation, seizures, status epilepticus, rhabdomyolysis, respiratory depression, urinary retention, confusion, delirium and/or agitation, coma and death. Patients with pre-existing severe cardiovascular disease may be at an increased risk of the effects of overdose. (see section 4.4).

Management of overdose

There is no specific antidote to **QUETIAPINE UNICORN.**

In cases of severe signs, the possibility of multiple medicine involvement should be considered, and intensive care procedures adopted, including establishing and maintaining a patent airway, ensuring adequate oxygenation and ventilation, and monitoring and support of the cardiovascular system.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:

Antipsychotics; Diazepines, oxazepines and thiazepines

Category and Class:

2.6.5 Central nervous system depressants: Miscellaneous structures**.**

Quetiapine interacts and blocks with various neurotransmitter receptors and is a dibenzothiapine atypical antipsychotic medicine. Quetiapine is an antagonist at serotonin receptors (5-HT_{1A} and 5-HT_2), dopamine D_1 and D_2 histaminergic (H_1), and adrenergic alpha-1 receptors, and alpha-2 receptors. Quetiapine has no significant affinity for cholinergic muscarinic or benzodiazepine receptors. Quetiapine occupies the $5HT_2$ and D_2 receptors for up to 12 hours after dosing when given twice daily.

5.2 Pharmacokinetic properties

Absorption

Quetiapine is well absorbed after oral doses.

Distribution

It is widely distributed throughout the body and is about 65 % to 83 % bound to plasma proteins. Quetiapine reaches peak plasma levels well within 1,5 hours. The bioavailability of quetiapine is not significantly affected by administration with food.

Biotransformation

Quetiapine is extensively metabolised following oral administration by hepatic cytochrome P450, CYP3A4 isoenzyme and oxidation to inactive and readily excreted sulphoxide and acidic derivatives.

Elimination

It is excreted mainly via the urine (73 %) and about 20 % in the faeces. The elimination half-life of quetiapine is approximately 6 to 7 hours.

Gender

The pharmacokinetics of quetiapine is similar in both genders.

Elderly

The mean clearance of quetiapine in the elderly is approximately was 30 % to 50 % less than in younger patients.

Renal and hepatic impairment

In patients with severe renal impairment (creatinine clearance less than 30 ml/min/1,73 m^2) and in subjects with hepatic impairment (stable alcoholic cirrhosis), the mean plasma clearance of quetiapine is reduced. (see section 4.2).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core

Dibasic calcium phosphate dehydrate, microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, povidone and magnesium stearate.

Coating

QUETIAPINE 25 UNICORN: Opadry orange which contains hypromellose, titanium dioxide, macrogol, iron oxide yellow, iron oxide red.

QUETIAPINE 100 UNICORN: Opadry yellow which contains hypromellose, titanium dioxide, macrogol, iron oxide yellow.

QUETIAPINE 200 UNICORN and QUETIAPINE 300 UNICORN: Opadry white which contains hypromellose, titanium dioxide, macrogol.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store at or below 25 °C.

Keep blisters in outer carton until required for use.

Do not use the tablets after the expiry date printed on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6.5 Nature and contents of container

QUETIAPINE UNICORN tablets are packed into white opaque PVC / silver aluminium blisters strips, containing 10 tablets each.

Pack sizes

QUETIAPINE 25 UNICORN:

Pack sizes of 100 tablets (10 blister strips of 10 tablets)

QUETIAPINE 100 UNICORN:

Pack sizes of 90 tablets (9 blister strips of 10 tablets)

QUETIAPINE 200 UNICORN:

Pack sizes of 60 tablets (6 blister strips of 10 tablets)

QUETIAPINE 300 UNICORN:

Pack sizes of 60 tablets (6 blister strips of 10 tablets)

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Unicorn Pharmaceuticals (Pty) Ltd

Corner Searle & Pontac Streets,

Cape Town,

South Africa, 8001

enquiries@unicornpharma.co.za

8. REGISTRATION NUMBER(S)

QUETIAPINE 25 UNICORN: A46/2.6.5/0946

QUETIAPINE 100 UNICORN: A46/2.6.5/0947

QUETIAPINE 200 UNICORN: A46/2.6.5/0948

QUETIAPINE 300 UNICORN: A46/2.6.5/0949

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21 February 2021

10. DATE OF REVISION OF THE TEXT

Not applicable