SCHEDULING STATUS:
S5

PROPRIETARY NAME AND DOSAGE FORM:
QUETIAPINE BIOTECH 25 (Film-coated Tablet)
QUETIAPINE BIOTECH 100 (Film-coated Tablet)
QUETIAPINE BIOTECH 200 (Film-coated Tablet)
QUETIAPINE BIOTECH 300 (Film-coated Tablet)

COMPOSITION:
QUETIAPINE BIOTECH 25:
Each film-coated tablet contains 25 mg of quetiapine free base.
QUETIAPINE BIOTECH 100:
Each film-coated tablet contains 100 mg of quetiapine free base.
QUETIAPINE BIOTECH 200:
Each film-coated tablet contains 200 mg of quetiapine free base.
QUETIAPINE BIOTECH 300:
Each film-coated tablet contains 300 mg of quetiapine free base.
Excipients:
Lactose monohydrate, microcrystalline cellulose, povidone K-25, sodium starch glycolate (type A), glycerol dibehanate, colloidal anhydrous silica, magnesium stearate, opadry II pink (colourant for 25 mg strength), opadry II yellow (colourant for 100 mg strength), opadry II white (colourant for 200 mg and 300 mg strengths), purified water.
Contains sugar.

PHARMACOLOGICAL CLASSIFICATION:
A 2.6.5 Central nervous system depressants: Miscellaneous structures

PHARMACOLOGICAL ACTION :
Pharmacodynamic properties
Quetiapine is a dibenzothiazepine atypical antipsychotic agent which interacts with a broad range of neurotransmitter receptors. It is reported to have a higher affinity for serotonin ($5HT_2$) receptors in the brain than it does for dopamine D_1 and D_2 receptors in the brain. Quetiapine has a high affinity at histaminergic and adrenergic alpha-1 receptors, with a lower affinity at adrenergic alpha-2 receptors, but no appreciable affinity at cholinergic muscarinic or benzodiazepine receptors. Quetiapine, when given twice a day, maintains $5HT_2$ and D_2 receptor occupancy for up to 12 hours after dosing.
Pharmacokinetic properties
Quetiapine is well absorbed and extensively metabolised following oral administration, and widely distributed throughout the body. Peak plasma concentrations are reached in about 1,5 hours. It is about 83 % bound to plasma proteins. Quetiapine is extensively metabolised in the liver by sulfoxidation mediated mainly by the cytochrome P450 isoenzyme CYP3A4 and by oxidation.
The bioavailability of quetiapine is not significantly affected by administration with food. It is excreted mainly as inactive metabolite with about 73 % of a dose appearing in the urine and about 20 % in the faeces. The elimination half-life has been reported to be approximately 7 hours. The pharmacokinetics of quetiapine are variable but do not differ significantly between men and women.
The mean clearance of quetiapine in the elderly is approximately 30 % to 50 % lower than that seen in adults aged 18 to 65 years.
The mean clearance of quetiapine was reduced by approximately 25 % in subjects with severe renal impairment (creatinine clearance less than 30 ml/min/1,73 m^2) and in subjects with hepatic impairment (stable alcoholic cirrhosis), but the individual clearance values are within the range for normal subjects.

INDICATIONS:
QUETIAPINE BIOTECH is indicated for the treatment of schizophrenia.
QUETIAPINE BIOTECH is also indicated for the treatment of manic episodes associated with a bipolar disorder. Safety and efficacy beyond 12 weeks has not been demonstrated.

CONTRA-INDICATIONS:
QUETIAPINE BIOTECH is contra-indicated in patients who are hypersensitive to quetiapine or any component of QUETIAPINE BIOTECH.
QUETIAPINE BIOTECH should not be used in patients with advanced liver and renal function impairment.
Pregnancy and lactation, as safety has not been demonstrated.
Safety and efficacy in children and adolescents under the age of 18 years have not been demonstrated. QUETIAPINE BIOTECH is not indicated for use in elderly patients with dementia-related psychosis.
Concomitant administration of cytochrome P450 3A4 inhibitors, such as HIV-protease inhibitors, azole-antifungal agents, erythromycin, clarithromycin and nefazodone, is contraindicated.

WARNINGS:
Hyperglycaemia and Diabetes mellitus:
Hyperglycaemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with QUETIAPINE BIOTECH.
Patients with an established diagnosis of diabetes mellitus who are started on QUETIAPINE BIOTECH 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 QUETIAPINE BIOTECH should be monitored for symptoms of hyperglycaemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycaemia during treatment with QUETIAPINE BIOTECH should undergo fasting blood glucose testing. In some cases, hyperglycaemia has resolved when QUETIAPINE BIOTECH was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect medicine.
Where the use of QUETIAPINE BIOTECH in the elderly is considered essential, the lowest effective dose should be used. These patients should be carefully monitored to avoid or reduce hypotension, gait disturbances, over-sedation and complications associated with hyperglycaemia. Before prescribing QUETIAPINE BIOTECH, clinicians are advised to carefully assess the risks and benefits of the use of QUETIAPINE BIOTECH in elderly patients with dementia. In these cases, the risk prediction for stroke in the individual patient (e.g. hypertension, diabetes, current smoking, atrial fibrillation and age >80 years) must be taken into account.

INTERACTIONS:
The central effects of other CNS depressants, including alcohol, may be enhanced by QUETIAPINE BIOTECH. Caution should be taken when co-administering QUETIAPINE BIOTECH with carbamazepine (a known hepatic enzyme inducer) as it can cause increases in clearance of QUETIAPINE BIOTECH. As a consequence of this interaction lower plasma concentrations can occur, and hence in each patient, consideration for a higher dose of QUETIAPINE BIOTECH, depending on clinical response, should be given. The recommended maximum daily dose for the applicable indication should be noted (see DOSAGE AND DIRECTIONS FOR USE).
The pharmacokinetics of lithium was not altered when co-administered with QUETIAPINE BIOTECH.
The pharmacokinetics of sodium valproate and QUETIAPINE BIOTECH were not altered to a clinically relevant extent when co-administered.
The pharmacokinetics of QUETIAPINE BIOTECH was not significantly altered after co-administration with antipsychotics such as risperidone or haloperidol. But co-administration of QUETIAPINE BIOTECH and thioridazine caused an increase in clearance of QUETIAPINE BIOTECH.
QUETIAPINE BIOTECH should be used with caution in patients receiving antihypertensives or medicines that prolong the QT interval (see SIDE EFFECTS AND SPECIAL PRECAUTIONS).
QUETIAPINE BIOTECH may antagonise the actions of dopaminergics, such as levodopa.
Co-administration of QUETIAPINE BIOTECH with another microsomal enzyme inducer, phenytoin, can also cause increases in clearance of QUETIAPINE BIOTECH. Increased doses of QUETIAPINE BIOTECH may be required to maintain control of psychotic symptoms in patients co-administered QUETIAPINE BIOTECH and other hepatic enzyme inducers (e.g. barbiturates, rifampicin etc.). The dose of QUETIAPINE BIOTECH may need to be reduced if phenytoin, carbamazepine or other hepatic enzyme inducers are withdrawn and replaced with a non-inducer (e.g. sodium valproate).
The co-administration of ketoconazole and QUETIAPINE BIOTECH may result in a significant (5-fold) increase in the AUC of QUETIAPINE BIOTECH. For this reason concomitant use of QUETIAPINE BIOTECH and potent CYP3A4 inhibitors is contraindicated (see CONTRA-INDICATIONS).
Clearance of QUETIAPINE BIOTECH was decreased by 20 % when co-administered with cimetidine 400 mg per day.
Mean clearance of lorazepam was decreased by 20 % when co-administered with QUETIAPINE BIOTECH 25 mg three times a day.

PREGNANCY AND LACTATION:
As safety has not been demonstrated, QUETIAPINE BIOTECH is contra-indicated during pregnancy and lactation (see CONTRA-INDICATIONS).

DOSAGE AND DIRECTIONS FOR USE:
QUETIAPINE BIOTECH should be administered twice daily, with or without food.
Adult treatment of schizophrenia:
For the treatment of schizophrenia the total daily dose for the first 4 days of therapy is 50 mg (Day 1), 100 mg (Day 2), 200 mg (Day 3) and 300 mg (Day 4). From day 4 onwards, the dose should be titrated to the effective dose range of 300-450 mg/day. However this may be adjusted, depending on the clinical response and tolerability of the individual patient, within the range 150-750 mg/day.
Adult treatment of manic episodes associated with bipolar disorder:
For the treatment of manic episodes associated with bipolar disorder, the total daily dose for the first 4 days of therapy is 100 mg (Day 1), 200 mg (Day 2), 300 mg (Day 3) and 400 mg (Day 4). Further dosage adjustments up to 800 mg/day by Day 6 should be increments of 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.
Elderly:
QUETIAPINE BIOTECH should be used with caution in the elderly, especially during the initial dosing period. Elderly patients should be started on QUETIAPINE BIOTECH 25 mg/day. The dose should be increased daily, in increments of 25-50 mg, to an effective dose, depending on the clinical response and the tolerance of the individual patient.
Renal and hepatic impairment:
Clearance of quetiapine is reduced by approximately 25 % in patients with renal or hepatic impairment. Quetiapine is extensively metabolised by the liver, and therefore should be used with caution in patients with known hepatic impairment. Patients with renal or hepatic impairment should be started on QUETIAPINE BIOTECH 25 mg/day. The dose should be increased daily in increments of 25-50 mg, to an effective dose.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
Side effects:
The most commonly reported adverse drug reactions (ADRs) with QUETIAPINE BIOTECH are somnolence, dizziness, dry mouth, asthenia, constipation, tachycardia, orthostatic hypotension and dyspepsia. Weight gain, syncope, neuroleptic malignant syndrome, leucopenia, neutropenia and peripheral oedema have been associated with QUETIAPINE BIOTECH.
Adverse reactions arranged by system organ class are as follows:
Nervous system disorders
Frequent: Dizziness (see SPECIAL PRECAUTIONS); somnolence (see SPECIAL PRECAUTIONS); headache, syncope (see SPECIAL PRECAUTIONS), dysarthria, anxiety, extrapyramidal symptoms (akathisia, akinesia, cogwheel rigidity, extrapyramidal syndrome, hypertonia, hypokinesia, neck rigidity and tremor)
Less frequent: Seizure (see SPECIAL PRECAUTIONS), restless leg syndrome, tardive dyskinesia, neuroleptic malignant syndrome.
Psychiatric disorders
Frequent: Abnormal dreams, nightmares.
Less frequent: Somnambulism and other related events.
Blood and lymphatic system disorder
Frequent: Leucopenia (see SPECIAL PRECAUTIONS).
Less frequent: Eosinophilia, neutropenia (see SPECIAL PRECAUTIONS), thrombocytopenia.
Frequency unknown: Agranulocytosis.
Cardiac disorders
Frequent: Tachycardia; palpitations.
Frequency unknown: Prolongation of QT interval (see SPECIAL PRECAUTIONS), ventricular dysrhythmia; sudden unexplained death; cardiac arrest and Torsades de Pointes (as class effects of neuroleptics).
Gastrointestinal disorders
Frequent: Dry mouth; constipation; dyspepsia; vomiting.
Less frequent: Abdominal pain; dysphagia; decreased appetite.

General disorders and administration site conditions
Frequent: Asthenia; peripheral oedema; withdrawal (discontinuation) symptoms; pyrexia; irritability.
Less frequent: Myalgia; hypothermia.
Hepato-biliary disorders
Less frequent: Jaundice; hepatitis.
Respiratory, thoracic, and mediastinal disorders
Frequent: Rhinitis.
Frequency unknown: Chest pain; dyspnoea.
Immune system disorders
Less frequent: Hypersensitivity (angioedema, anaphylaxis, urticaria/rash); Stevens-Johnson syndrome.
Vascular disorders
Frequent: Orthostatic hypotension (see SPECIAL PRECAUTIONS).
Less frequent: Venous thromboembolism.
Investigations
Frequent: Weight gain (see SPECIAL PRECAUTIONS), elevations in serum transaminases (ALT, AST) (see SPECIAL PRECAUTIONS), elevations in serum triglyceride levels; elevations in total cholesterol (predominantly LDL cholesterol); decreases in HDL cholesterol; decreased neutrophil count; increased blood glucose to hyperglycaemic level; elevations in serum prolactin; decreases in thyroid hormone levels as described in text below; decreased haemoglobin.
Less frequent: Elevations in gamma GT levels (see SPECIAL PRECAUTIONS), platelet count decreased; elevations in blood creatinine phosphokinase.
Reproductive system and breast disorders
Less frequent: Sexual dysfunction; priapism; galactorrhoea; breast swelling; menstrual disorder.
Endocrine disorders
Less frequent: Inappropriate antidiuretic hormone secretion.
Frequency unknown: Hypothyroidism.
Musculoskeletal, connective tissue and bone disorders
Less frequent: Back pain; rhabdomyolysis.
Metabolism and nutrition disorders
Frequent: Increased appetite
Less frequent: Diabetes mellitus (or exacerbation of pre-existing diabetes); hyponatraemia.
Ear and labyrinth disorders
Frequency unknown: Ear pain.
Eye disorders
Frequent: Dry eyes, blurred vision.
Frequency Unknown: Cataract formation.
Renal and urinary disorders
Frequency unknown: Urinary tract infection
QUETIAPINE BIOTECH was associated with dose-related decreases in thyroid hormone levels, particularly total T4 and free T4. The reduction in total T4 and free T4 was maximally within the first two to four weeks of QUETIAPINE BIOTECH treatment with no further reduction during long-term treatment. There was no evidence of clinical significant changes in TSH concentration over time. In nearly all cases, cessation of QUETIAPINE BIOTECH treatment has been associated with reversal of the effects on total and free T4, irrespective of the duration of treatment. Smaller decreases in total and reverse T3 were seen only at higher doses. Levels of TBG were unchanged and in general, reciprocal increases in TSH were not observed, with any indication that QUETIAPINE BIOTECH causes clinically relevant hypothyroidism.
Special precautions:
Somnolence may occur, usually during the first 2 weeks of treatment and generally resolves with the continued administration of QUETIAPINE BIOTECH. Resolution of leucopenia and/or neutropenia may follow cessation of therapy with QUETIAPINE BIOTECH. Although a causal relationship could be established, the possibility that QUETIAPINE BIOTECH may be implicated cannot be excluded.
Weight gain occurs predominantly during the early weeks of treatment.
QUETIAPINE BIOTECH may induce orthostatic hypotension, associated with dizziness, tachycardia and, in some patients, syncope, especially during the initial dose-titration period.
Seizures:
Caution is recommended when treating patients with a history of seizures.
Concomitant illness:
QUETIAPINE BIOTECH should be used with caution in patients with known cardiovascular disease, cerebrovascular disease, or other conditions predisposing to hypotension. QUETIAPINE BIOTECH may induce orthostatic hypotension especially during the initial dose-titration period; this is more common in elderly patients than in younger patients. Dose reduction or more gradual titration should be considered if this occurs. A slower titration regimen could be considered in patients with underlying cardiovascular disease.
Dysphagia and aspiration have been reported with quetiapine as in QUETIAPINE BIOTECH. Although a causal relationship with aspiration pneumonia has not been established, QUETIAPINE BIOTECH should be used with caution in patients at risk for aspiration pneumonia.
QT Prolongation:
Caution should be exercised when QUETIAPINE BIOTECH is prescribed in patients with cardiovascular disease or family history of QT prolongation. Also, caution should be exercised when QUETIAPINE BIOTECH is prescribed either with medicines known to increase QT interval, or with concomitant neuroleptics, especially in patients with increased risk of QT prolongation, i.e. the elderly, in patients with congenital long QT syndrome, congestive heart failure, heart hypertrophy, hypokalaemia or hypomagnesaemia (see INTERACTIONS).
Tardive dyskinesia:
There is a potential for QUETIAPINE BIOTECH to cause tardive dyskinesia. If signs and symptoms of tardive dyskinesia appear, discontinuation of QUETIAPINE BIOTECH should be considered.
The symptoms of tardive dyskinesia can worsen or even arise after discontinuation of treatment (see SIDE EFFECTS).
Severe neutropenia:
Severe neutropenia (neutrophil count $<0,5 \times 10^9/\ell$) has been reported. Most cases of severe neutropenia have occurred within a couple of months of starting therapy with quetiapine. Resolution of leucopenia and/or neutropenia may follow cessation of therapy with QUETIAPINE BIOTECH. Possible risk factors for neutropenia include pre-existing low white cell count (WBC) and history of medicine induced neutropenia. QUETIAPINE BIOTECH should be discontinued in patients with a neutrophil count $<1,0 \times 10^9/\ell$. Patients should be observed for signs and symptoms of infection and neutrophil counts followed (until they exceed $<1,5 \times 10^9/\ell$).
Lipids:
Increases in triglycerides, LDL and total cholesterol, and decreases in HDL cholesterol have been observed with quetiapine, as in QUETIAPINE BIOTECH (see 'Side effects"). Lipid changes should be managed as clinically appropriate.
Acute withdrawal reactions:
Acute withdrawal symptoms such as insomnia, nausea, headache, diarrhoea, vomiting, dizziness and irritability may occur after abrupt cessation of QUETIAPINE BIOTECH. Recurrence of psychotic symptoms may also occur, and the emergence of involuntary movement disorders (such as akathisia, dystonia and dyskinesia) has been reported. Gradual withdrawal over a period of at least one to two weeks is advisable.
Elderly patients with dementia-related psychosis:
QUETIAPINE BIOTECH is not approved for the treatment of patients with dementia-related psychosis (see CONTRA-INDICATIONS).
With some atypical antipsychotics, an approximately 3-fold increased risk of cerebrovascular adverse events has been seen in the dementia population. The mechanism for this increased risk is not known. QUETIAPINE BIOTECH should be used with caution in patients with risk factors for stroke.
Hepatic effects:
If jaundice develops, QUETIAPINE BIOTECH should be discontinued.
Venous thromboembolism (VTE):
Cases of venous thromboembolism (VTE) have been reported. Since patients treated with antipsychotics often present with acquired risk factors for VTE, all possible risk factors for VTE should be identified before and during treatment with QUETIAPINE BIOTECH and preventative measures undertaken.
Suicide/suicidal thoughts or clinical worsening:
Suicide and related events may occur in patients <18 years of age (see CONTRA-INDICATIONS). Patients being treated with QUETIAPINE BIOTECH should therefore be observed closely for suicidality or clinical worsening.
Neuroleptic malignant syndrome:
Neuroleptic malignant syndrome has been associated with QUETIAPINE BIOTECH treatment. Clinical manifestations include hyperthermia, altered mental status, muscular rigidity, autonomic instability and increased creatine phosphokinase. In such an event, QUETIAPINE BIOTECH should be discontinued and appropriate medical treatment given.
In patients with Alzheimer's dementia dysphagia associated with use of antipsychotic medications may increase risk of aspiration pneumonia.
Patients with a history of substance abuse should be observed closely for signs of misuse or abuse of QUETIAPINE BIOTECH.
Lactose:
QUETIAPINE BIOTECH tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption should not take QUETIAPINE BIOTECH.
Effect on ability to drive and use machines:
QUETIAPINE BIOTECH may cause dizziness and somnolence which may interfere with activities requiring mental alertness. Therefore, patients should be advised not to drive or operate machinery, until individual susceptibility is known.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
There is no specific antidote to QUETIAPINE BIOTECH. Treatment is symptomatic and supportive.
In general, reported signs and symptoms are those resulting from an exaggeration of the quetiapine's known pharmacological effects, i.e., drowsiness and sedation, tachycardia and hypotension.
Patients with pre-existing severe cardiovascular disease may be at an increased risk of the effects of overdose.

IDENTIFICATION:
QUETIAPINE BIOTECH 25: Round biconvex pink film-coated tablet
QUETIAPINE BIOTECH 100: Round biconvex yellow film-coated tablet
QUETIAPINE BIOTECH 200: Round biconvex white film-coated tablet
QUETIAPINE BIOTECH 300: Oblong biconvex white film-coated tablet

PRESENTATION:
30; 60; 90 or 100 Tablets are packed in Polyamide/Aluminium/PVC blister strips or PVC/aluminium and aluminium strips. Each containing ten tablets. The blisters are packed in an outer carton.

STORAGE INSTRUCTIONS:
Store at or below 25 °C. Keep blisters in the outer carton until required for use.
KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBERS:
QUETIAPINE BIOTECH 25 (Film-coated Tablet) : 45/2.6.5/0212
QUETIAPINE BIOTECH 100 (Film-coated Tablet) : 45/2.6.5/0213
QUETIAPINE BIOTECH 200 (Film-coated Tablet) : 45/2.6.5/0214
QUETIAPINE BIOTECH 300 (Film-coated Tablet) : 45/2.6.5/0215

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
BIOTECH LABORATORIES (PTY) LTD
Ground Floor, Block K West, Central Park
400 16th Road, Randjespark, Midrand, 1685
South Africa

DATE OF PUBLICATION OF THE PACKAGE INSERT:
Date of registration: 31 July 2014
Date of latest revision of the text as approved by Council: 31 July 2014
Date of notification with regard to amended Reg. 9 and 10: 6 May 2016

SKEDULERINGSTATUS:
S5

EIENDOMSNAAM EN DOSEERVORM:
QUETIAPINE BIOTECH 25 (Film-bedekte Tablet)
QUETIAPINE BIOTECH 100 (Film-bedekte Tablet)
QUETIAPINE BIOTECH 200 (Film-bedekte Tablet)
QUETIAPINE BIOTECH 300 (Film-bedekte Tablet)

SAMESTELLING:
QUETIAPINE BIOTECH 25:
Elke film-bedekte tablet bevat 25 mg quetiapine vry basis.
QUETIAPINE BIOTECH 100:
Elke film-bedekte tablet bevat 100 mg quetiapine vry basis.
QUETIAPINE BIOTECH 200:
Elke film-bedekte tablet bevat 200 mg quetiapine vry basis.
QUETIAPINE BIOTECH 300:
Elke film-bedekte tablet bevat 300 mg quetiapine vry basis.
Onaktiewe bestanddele:
Laktose monohidraat, mikrokristallyne sellulose, povidoon K-25, natrium stysel glikolaat (tipe A), gliserol dibehanaat, kolloïdale anhidriese silika, magnesiumstearaat, opadry II pienk (kleurstof vir die 25 mg sterkte), opadry II geel (kleurstof vir die 100 mg sterkte), opadry II wit (kleurstof vir die 200 mg en 300 mg sterktes), gesuiwerde water.
Bevat suiker.

FARMAKOLOGIESE KLASSIFIKASIE:
A 2.6.5 Depressante van die sentrale senuweestelsel: Diverse strukture

FARMAKOLOGIESE WERKING
Farmakodinamiese eienskappe
Quetiapine is 'n dibensodiasepien atipiese antipsigotiese middel wat met 'n wye reeks neurotransmitter-reseptore interreageer. Quetiapine vertoon 'n hoër affiniteit vir serotonien ($5HT_2$) reseptore in die brein as vir dopamien D_1 and D_2 reseptore in die brein. Quetiapine het ook hoë affiniteit vir histamine en adrenergiese alfa-1 reseptore, met 'n laer affiniteit vir adrenergiese alfa-2 reseptore, maar geen beduidende affiniteit vir cholinergiese muskarien- of bensodiasepien-reseptore nie. Quetiapine, wanneer twee maal daagliks gegee, beset $5HT_2$ en D_2 reseptore vir tot 12 uur ná dosering.
Farmakokinetiese eienskappe
Quetiapine word na mondelikse toediening geabsorbeer, regdeur die liggaam versprei en omvattend gemetaboliseer. Piek plasmakonsentrasies word binne omtrent 1,5 ure bereik. Dit word omtrent 83 % verbind aan plasma proteïene. Quetiapine word omvattend in die lewer gemetaboliseer deur sulfoksidasie wat hoofsaaklik deur die sitochroom P450 isoënsiem CYP3A4 en deur middel van oksidasie plaasvind.
Die biobeskikbaarheid van quetiapine word nie beduidend beïnvloed deur toediening saam met voedsel nie. Dit word hoofsaaklik as onaktiewe metaboliet uitgeskei met omtrent 73 % van die dosis wat in die uriene verskyn en 20 % daarvan in die feses. Die eliminasiehalfleeftyd van quetiapine is ongeveer 7 uur. Die farmakokinetika van quetiapine wissel maar verskil nie beduidend tussen mans en vroue nie.
Die gemiddelde opruiming van quetiapine by bejaardes is ongeveer 30 % tot 50 %, laer as dié waargeneem by volwassenes tussen die ouderdomme 18 tot 65 jaar.
Die gemiddelde opruiming van quetiapine is met ongeveer 25 % verlaag by persone met erge inkorting van nierfunksie (kreatinienopruiming minder as 30 ml/min/1,73 m^2) en by persone met inkorting van lewerfunksie (stabiele alkoholsirrose), maar die individuele waardes van opruiming is binne die grense vir normale persone.

INDIKASIES:
QUETIAPINE BIOTECH is aangedui vir die behandeling van skisofrenie.
QUETIAPINE BIOTECH is ook aangedui vir die behandeling van maniese episodes geassosieer met 'n bipolêre versteuring. Veiligheid en effektiwiteit vir gebruik langer as 12 weke is nog nie bewys nie.

KONTRA-INDIKASIES:
QUETIAPINE BIOTECH is teenaangedui in pasiënte wat hipersensitief is vir enige komponent van hierdie geneesmiddel.
QUETIAPINE BIOTECH moet nie gebruik word in pasiënte met gevorderde inkorting van lewer- en nierfunksie nie.
Die veiligheid van gebruik gedurende swangerskap en borsvoeding is nog nie vasgestel nie.
Veiligheid en doeltreffendheid van gebruik in kinders en adolessente onder die ouderdom van 18 jaar is nog nie vasgestel nie.
QUETIAPINE BIOTECH word nie aangedui vir gebruik in pasiënte met dementia-
verwante psigose nie.
Die gelyktydige gebruik van sitochroom P450 3A4 inhibeerders, soos HIV-protease inhibeerders, asool-antifungus middels, eritromisien, klaritromisien en nefasodoon is teenaangedui.

WAARSKUWINGS:
Hiperglisemie en Diabetes mellitus:
Hiperglisemie, in sommige gevalle uitermatig en geassosieer met ketoasidose of hiperosmolêre koma of die dood, is aangemeld by pasiënte wat met QUETIAPINE BIOTECH behandel is.
Pasiënte met 'n bevestigde diagnose van diabetes mellitus wat met QUETIAPINE BIOTECH behandeling begin, moet gereeld gemonitor word vir 'n agteruitgang van glukose beheer.
Pasiënte met 'n risiko faktor om diabetes mellitus te ontwikkel (b.v. obesiteit, familiegeskiedenis van diabetes) wat behandeling met QUETIAPINE BIOTECH begin, moet gemonitor word vir simptome van hiperglisemie insluitende polidipsie, poliurie, polifagie en swakheid. Pasiënte wat simptome van hiperglisemie ontwikkel gedurende behandeling met QUETIAPINE BIOTECH, moet vastende bloedglukose toetsing ondergaan. Hiperglisemie het in sommige gevalle opgeklaar nadat
behandeling met QUETIAPINE BIOTECH gestaak is; sommige pasiënte het egter voortsetting van antidiabetiese behandeling nodig gehad, ondanks staking van die geneesmiddel waaroor daar onsekerheid was.
Wanneer die gebruik van QUETIAPINE BIOTECH in bejaardes as noodsaaklik beskou word, moet die laagste effektiewe dosis gebruik word. Hierdie pasiënte moet noukeurig gemonitor word om hipotensie, gang-
versteurings, oor-sedasie en komplikasies wat met hiperglisemie gepaard gaan, te verminder of vermy. Voordat QUETIAPINE BIOTECH voorgeskryf word, word klinici aangeraai om die voordele en nadele van die gebruik van QUETIAPINE BIOTECH in bejaarde pasiënte met dementia noukeurig te evalueer. Die risiko van 'n beroerte in individuele pasiënte (b.v. hipertensie, diabetes, huidige roker, atriële fibrillasie en pasiënte ouer as 80 jaar) moet in hierdie gevalle in berekening geneem word.

INTERAKSIES:
Die sentrale uitwerking van ander SSS depressante, insluitend alkohol, kan deur die gebruik van QUETIAPINE BIOTECH verhoog word. Let daarop dat wanneer QUETIAPINE BIOTECH saam met karbamasepien ('n bekende lewerensiem induseerder) toegedien word, dit 'n verhoging in die opruiming van QUETIAPINE BIOTECH tot gevolg kan hê. As gevolg van hierdie interaksie kan laer plasma konsentrasies voorkom, daarom moet 'n hoër dosis van QUETIAPINE BIOTECH oorweeg word vir elke afsonderlike pasiënt, afhangende van die kliniese reaksie. Die voorgestelde maksimum daaglikse dosis vir die toepaslike indikasie moet in ag geneem word (sien DOSIS EN GEBRUIKSAANWYSINGS).
Die farmakokinetika van litium het nie verander wanneer gelyktydig met QUETIAPINE BIOTECH toegedien is nie. Die farmakokinetika van natriumvalproaat en QUETIAPINE BIOTECH het nie verander in 'n kliniese relevante mate wanneer gelyktydige gebruik is nie. Die farmakokinetika van QUETIAPINE BIOTECH het nie aansienlik verander na gelyktydige gebruik van antipsigotiese middels soos risperidoon of haloperidol nie. Die gelyktydige gebruik van QUETIAPINE BIOTECH en tioridasien kan wel 'n verhoogde opruiming van QUETIAPINE BIOTECH veroorsaak.
QUETIAPINE BIOTECH moet met omsigtigheid gebruik word in pasiënte wat antihipertensie medikasie gebruik of medisyne wat die QT interval verleng (sien NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS).
QUETIAPINE BIOTECH mag die werking van dopaminergiese middels soos levodopa teenwerk. Gesamentlike toediening van QUETIAPINE BIOTECH met 'n ander mikrosomale ensiminduseerder, fenitoïen, kan ook toenames in opruiming van QUETIAPINE BIOTECH veroorsaak. Verhoogde dosisse van QUETIAPINE BIOTECH mag nodig wees om die beheer van psigotiese simptome te handhaaf in pasiënte wat QUETIAPINE BIOTECH saam met ander hepatiese ensiminduseerders (b.v. barbiturate en rifampisien) ontvang. Dit mag nodig wees om die dosis van QUETIAPINE BIOTECH te verminder indien fenitoïen, karbamasepien of ander hepatiese ensiminduseerders onttrek word en met 'n nie-induseerder (b.v. natriumvalproaat) vervang word.
Die gesamentlike toediening van ketokonasool en QUETIAPINE BIOTECH kan lei tot 'n beduidende (5-voudige) vermeerdering in die AOK van QUETIAPINE BIOTECH. Vir hierdie rede word die gesamentlike gebruik van QUETIAPINE BIOTECH en kragtige CYP3A4 inhibeerders teenaangedui (sien KONTRA-INDIKASIES).
Opruiming van QUETIAPINE BIOTECH het met 20 % afgeneem toe dit saam met simetidien 400 mg per dag toegedien is.
Die gemiddelde opruiming van lorasepam het afgeneem met 20 % toe dit saam met QUETIAPINE BIOTECH 25 mg drie maal per dag toegedien is.

SWANGERSKAP EN BORSVOEDING:
Veiligheid van gebruik is nog nie gedemonstreer nie, QUETIAPINE BIOTECH is teenaangedui tydens swangerskap en borsvoeding. (sien KONTRA-INDIKASIES).

DOSERING EN GEBRUIKSAANWYSINGS:
QUETIAPINE BIOTECH moet twee maal per dag, met of sonder voedsel toegedien word.
Behandeling van skisofrenie in volwassenes:
Vir die behandeling van skisofrenie is die totale daaglikse dosis vir die eerste 4 dae van terapie 50 mg (Dag 1), 100 mg (Dag 2), 200 mg (Dag 3) en 300 mg (Dag 4). Van dag 4 af moet die dosis getitreer word na die effektiewe dosishoeveelheid van 300 – 450 mg per dag. Die dosis egter na tussen 150 – 750 mg/dag aangepas word, afhangede van die kliniese reaksie en verdraagsaamheid van die individuele pasiënt.
Behandeling van maniese episodes wat verband hou met bipolêre versteuring in volwassenes:
Vir die behandeling van maniese episodes geassosieer met bipolêre versteuring, is die totale daaglikse dosis vir die eerste 4 dae van terapie 100 mg (Dag 1), 200 mg (Dag 2), 300 mg (Dag 3) en 400 mg (Dag 4). Verdere dosisaanpassings tot 800 mg/dag teen Dag 6 moet met inkrements van nie groter nie as 200 mg/dag wees. Die dosis kan afhangde van die kliniese reaksie en verdraagsaamheid van die individuele pasiënt na tussen 200 – 800 mg/dag aangepas word. Die effektiewe dosis is gewoonlik tussen 400 – 800 mg/dag.
Bejaardes:
QUETIAPINE BIOTECH moet met omsigtigheid by bejaardes gebruik word, in die besonder tydens die aanvanklike doseringstydperk. Bejaarde pasiënte behoort met QUETIAPINE BIOTECH 25 mg/dag te begin. Die dosis moet daagliks verhoog word, met inkremente van 25 – 50 mg, tot 'n effektiewe dosis, afhangende van die kliniese reaksie en die verdraagsaamheid van die individuele pasiënt.
Inkorting van lewer- en nierfunksie:
Opruiming van quetiapine word verminder met ongeveer 25 % in pasiënte met lewer- of nierinkorting.
Quetiapine word omvattend gemetaboliseer deur die lewer, en moet dus met omsigtigheid gebruik word by pasiënte met ingekorte lewerfunksie. Pasiënte met inkorte nier- of lewerfunksie moet begin met 'n dosis van 25 mg QUETIAPINE BIOTECH per dag. Die dosis behoort daagliks met inkremente van 25 – 50 mg verhoog te word tot 'n effektiewe dosis bereik is.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Newe-effekte:
Die mees algemene gerapporteerde ongewenste geneesmiddel reaksies met die gebruik van QUETIAPINE BIOTECH is slaperigheid, duiseligheid, droë mond, astenie, hardlywigheid, tagikardie ortostatiese hipotensie en dispepsie. Toename in gewig, sinkopee, neuroleptiese kwaadaardige sindroom, leuko-penie, neutropenie en perifere edeem is al met die gebruik van QUETIAPINE BIOTECH geassosieer.
Die volgende ongewenste reaksies word volgens orgaanklas gelys:
Senuweestelsel afwykings
Algemeen: Duiseligheid (sien SPESIALE VOORSORGMAATREËLS); slaperigheid (sien SPESIALE VOORSORGMAATREËLS); hoofpyn, sinkopee (sien SPESIALE VOORSORGMAATREËLS), disartrie, angstigheid, ekstrapiramidale simptome (akatesie, akinesie, tandrat-rigiditeit, ekstrapiramidale sindroom, hipertonie, hipokinesie, nekrigiditeit en tremor)
Minder algemeen: Stuipe (sien SPESIALE VOORSORGMAATREËLS), rustelose bene sindroom, tardiewe diskinesie, neuroleptiese kwaadaardige sindroom.
Psigiatriese afwykings
Algemeen: Abnormale drome, nagmerries.
Minder algemeen: Slaapwandeling en ander verwante gebeure.
Bloed- en limfvatstelsel afwykings
Algemeen: Leukopenie (sien SPESIALE VOORSORGMAATREËLS).
Minder algemeen: Eosinofilie, neutropenie (sien SPESIALE VOORSORGMAATREËLS), trombositopenie.
Frekwensie onbekend: Agranulositose.
Kardiale afwykings
Algemeen: Tagikardie; palpitasies.
Frekwensie onbekend: Verlenging van die QT-interval (sien SPESIALE VOORSORGMAATREËLS), ventrikulêre disritmie; skielike onverklaarbare dood; hartaanval en Torsades de Pointes (as 'n gevolg van neuroleptika).

Gastroïntestinale afwykings
Algemeen: Droë mond; hardlywigheid; dispepsie; braking.
Minder algemeen: Abdominale pyn; disfagie; verminderde eetlus.
Algemene afwykings en toestande van die plek waar toegedien
Algemeen: Astenie; perifere edeem; onttrekkingsimptome (beëindiging); pireksie; prikkelbaarheid.
Minder algemeen: Mialgie; hipotermie.
Hepato-bilière afwykings
Minder algemeen: Geelsug; hepatitis.
Respiratoriese, torakale en mediastinale afwykings
Algemeen: Rinitis.
Frekwensie onbekend: Borspyn; dispnee.
Immuunstelsel afwykings
Minder algemeen: Hipersensitiwiteit (angioedeem, anafilakse, urtikarie/veluitslag; Stevens-Johnson sindroom.
Vaskulêre afwykings
Algemeen: Ortostatiese hipotensie (sien SPESIALE VOORSORGMAATREËLS).
Minder algemeen: Veneuse trombose.
Ondersoeke
Algemeen: Toename in gewig (sien SPESIALE VOORSORGMAATREËLS), verhoging in serumtransaminases (ALT, AST) (sien SPESIALE VOORSORGMAATREËLS), verhoging in serum trigliseriedvlakke; verhoging in totale cholesterol (hoofsaaklik LDL cholesterol); vermindering in HDL cholesterol; verminderde neutrofiel telling; verhoging in bloedglukose tot hiperglisemiese vlakke; verhoging in serum prolaktien; vermindering in tiroïed-hormoonvlakke soos in die teks hieronder beskryf; verminderde hemoglobien.
Minder algemeen: 'n Verhoging in gamma GT vlakke (sien SPESIALE VOORSORGMAATREËLS), verminderde plaatjietelling; verhoging in bloed kreatinienfosfokinase.
Voortplantingstelsel- en bors afwykings
Minder algemeen: Seksuele disfunksie; priapisme; galaktoree; swelling van die bors; menstruele versteuring.
Endokriene afwykings
Minder algemeen: Onvanpaste antidiuretiese hormoonvrystelling.
Frekwensie onbekend: Hipertiroïedisme.
Muskuloskeletale, bindweefsel- en beenafwykings
Minder algemeen: Rugpyn; rabdomiolise.
Metabolisme en voeding afwykings
Algemeen: Verhoogde eetlus.
Minder algemeen: Diabetes mellitus (of verergering van bestaande diabetes); hiponatremie.
Oor en labirint afwykings
Frekwensie onbekend: Oorpyn.
Oog afwykings
Algemeen: Droë oë, belemmerde sig.
Frekwensie onbekend: Vorming van katarakte.
Renale en urinêre afwykings
Frekwensie onbekend: Urienweg infeksie.
QUETIAPINE BIOTECH-behandeling is met dosisverwante afnames in tiroïedhormoonvlakke, veral totale T4 en vry T4 geassosieer. Die afname in totale T4 en vry T4 was die hoogste binne die eerste twee tot vier weke van QUETIAPINE BIOTECH behandeling met geen verdere vermindering gedurende langtermyn behandeling nie. Daar was geen bewyse van beduidende kliniese veranderinge in TSH konsentrasies met verloop van tyd nie. In byna alle gevalle is die beëindiging van QUETIAPINE BIOTECH behandeling geassosieer met die ommekeer van die uitwerking daarvan op totale en vry T4, ongeag van die duur van behandeling. Kleiner afnames in totale T3 en omgekeerde T3 is slegs by hoër dosisse waargeneem. TBG-vlakke was onveranderd en oor die algemeen is omgekeerde toenames in TSH nie waargeneem nie, en met geen aanduiding dat QUETIAPINE BIOTECH klinies relevante hipotiroïedisme veroorsaak nie.
Spesiale voorsorgmaatreëls:
Slaaperigheid kan gewoonlik gedurende die eerste 2 weke van behandeling voorkom, maar verdwyn gewoonlik met volgehoue gebruik van QUETIAPINE BIOTECH.
Resolusie van leukopenie en/of neutropenie mag volg op die beëndiging van QUETIAPINE BIOTECH behandeling. Alhoewel daar 'n oorsaaklike verband vasgestel kon word, is die moontlikheid dat QUETIAPINE BIOTECH geïmpliseer kan word nie uitgesluit nie.
Gewigstoename kom hoofsaaklik gedurende die eerste weke van behandeling voor.
QUETIAPINE BIOTECH kan moontlik aanleiding gee tot ortostatiese hipotensie, wat verband hou met duiseligheid, tagikardie en in sommige pasiënte, sinkopee veral tydens die aanvanklike dosis-titrasie tydperk.
Stuipe:
Omsigtigheid word aanbeveel by die behandeling van pasiënte met 'n geskiedenis van stuipe.
Meegaande siekte:
QUETIAPINE BIOTECH moet met omsigtigheid gebruik word by pasiënte met bekende kardiovaskulêre siekte, serebrovaskulêre siekte, of ander toestande wat tot hipotensie aanleiding kan gee. QUETIAPINE BIOTECH kan moontlik aanleiding gee tot ortostatiese hipotensie, in die besonder tydens die aanvanklike tydperk van dosis-titrasie; dit is meer algemeen by bejaarde pasiënte as by jonger pasiënte. 'n Dosisvermindering of meer geleidelike titrasie moet oorweeg word indien dit plaasvind. 'n Stadiger titrasie skedule kan oorweeg word in pasiënte met
onderliggende kardiovaskulêre siekte.
Disfagie en aspirasie is aangemeld met quetiapine gebruik, soos in QUETIAPINE BIOTECH.
Alhoewel 'n oorsaaklike verhouding met aspirasie longontsteking nog nie vasgestel is nie, moet QUETIAPINE BIOTECH met omsigtigheid gebruik word in pasiënte met 'n risiko vir die ontwikkeling daarvan.
QT Verlenging
Omsigtigheid moet uitgeoefen word wanneer QUETIAPINE BIOTECH voorgeskryf word aan pasiënte met kardiovaskulêre siekte of 'n familiegeskiedenis van QT verlenging. Daar moet ook met omsigtigheid te werk gegaan word wanneer QUETIAPINE BIOTECH saam met geneesmiddels wat daarvoor bekend is dat dit die QT interval verleng, of met gepaardgaande neuroleptiese middels, veral in pasiënte met 'n verhoogde risiko van QT verlenging, voorgeskryf word, soos in bejaardes, in pasiënte met kongenitale lang QT sindroom, kongestiewe hartversaking, hart hipertrofie, hipokalemie of hipomagnesemie (sien INTERAKSIES).
Tardiewe diskinesie:
Die moontlikheid bestaan dat QUETIAPINE BIOTECH tardiewe diskinesie kan veroorsaak. Indien tekens en simptome van tardiewe diskinesie verskyn moet die staking van QUETIAPINE BIOTECH behandeling oorweeg word. Die simptome van tardiewe diskinesie kan versleg of selfs weer te voorskyn kom nadat behandeling gestaak is (sien NEWE-EFFEKTE).
Erge neutropenie:
Erge neutropenie (neutrofieltelling < 0,5 X 10^9/ℓ) is al aangemeld. Meeste gevalle van erge neutropenie het plaasgevind binne 'n paar maande nadat behandeling met quetiapine begin is. Die staking van QUETIAPINE BIOTECH behandeling kan die resolusie van leukopenia en/of neutropenia tot gevolg hê. Moontlike risiko faktore sluit in voorafbestaande lae witbloedseltelling (WBS) en 'n geskiedenis van geneesmiddel geïnduseerde neutropenie. QUETIAPINE BIOTECH behandeling moet gestaak word in pasiënte met 'n neutrofieltelling van < 1,0 X 10^9/ℓ. Pasiënte moet waargeneem word vir tekens en simptome van infeksie, en neutrofieltellings moet gemonitor word (totdat dit < 1,5 X 10^9/ℓ oorskry).
Lipiede:
Stygings in trigliseriedvlakke, LDL en totale cholesterol, en vermindering in HDL cholesterol is opgemerk met die gebruik van quetiapine soos in QUETIAPINE BIOTECH (sien NEWE-EFFEKTE).
Lipied veranderinge moet beheer word soos klinies toepaslik.
Akute ontrekkingsreaksies:
Akute ontrekkingsimptome soos slapeloosheid, naarheid, hoofpyn, diarree, braking, duiseligheid en geïrriteerdheid mag plaasvind na skielike staking van QUETIAPINE BIOTECH. 'n Terugkeer van psigotiese simptome mag ook plaasvind, en die ontstaan van onwillekeurige bewegingsversteurings (soos akatisie, distonie en diskinesie) is ook aangemeld. Geleidelike onttrekking oor 'n tydperk van ten minste een tot twee weke word aanbeveel.
Bejaarde pasiënte met dementia-verwante psigose:
QUETIAPINE BIOTECH is nie goedgekeur vir die behandeling van pasiënte met dementia-verwante psigose nie (sien KONTRA-INDIKASIES).
'n Ongeveer 3-voudige verhoogde risiko van serebrovaskulêre newe-effekte is in die dementia bevolking gesien met die gebruik van sommige atipiese antipsigotiese middels. Die meganisme wat die risiko verhoog is nog nie bekend nie. QUETIAPINE BIOTECH moet met sorg gebruik word in pasiënte met risiko faktore vir beroerte.
Hepatiese effekte:
Indien geelsug ontwikkel moet QUETIAPINE BIOTECH behandeling gestaak word.
Veneuse tromboëmbolisme (VTE):
Gevalle van tromboëmbolisme is al aangemeld. Aangesien pasiënte wat met antipsigotiese middels behandel word meestal risiko faktore het vir verkryging van VTE, moet alle moontlike risiko faktore vir VTE geïdentifiseer word, voor en gedurende behandeling met QUETIAPINE BIOTECH, en voorkomende maatreëls moet geneem word.
Selfmoord/selfmoord gedagtes of kliniese verergering:
Selfmoord en gepaardgaande gebeure kan in pasiënte < 18 jarige ouderdom voorkom (sien KONTRA-INDIKASIES). Pasiënte wat met QUETIAPINE BIOTECH behandel word, moet daarom goed waargeneem word vir tekens van selfmoordneigings of kliniese verergering.
Neuroleptiese kwaadaardige sindroom:
Neuroleptiese kwaadaardige sindroom is geassosieer met QUETIAPINE BIOTECH behandeling. Kliniese manifestasies sluit in hipertermie, veranderde psigiese toestand, spier rigiditeit, outonomiese onstabiliteit en verhoogde kreatinien fosfokinase. In so 'n geval moet QUETIAPINE BIOTECH gestaak word en toepaslike mediese behandeling gegee word.
In pasiënte met Alzheimer's dementia disfagie wat geassosieer is met die gebruik van antipsigotiese medikasie mag die risiko verhoog word om aspirasie longontsteking te kry.
Pasiënte met 'n geskiedenis van dwelmmisbruik moet noukeurig waargeneem word vir tekens van misbruik van QUETIAPINE BIOTECH.
Laktose:
QUETIAPINE BIOTECH tablette bevat laktose. Pasiënte met 'n seldsame oorerflike probleem van galaktose intoleransie, die Lapp laktase tekort, of glukose-galaktose wanabsorpsie moet nie QUETIAPINE BIOTECH gebruik nie.
Uitwerking op die vermoë om 'n voertuig te bestuur en masjinerie te gebruik:
QUETIAPINE BIOTECH kan duiseligheid en lomerigheid veroorsaak, wat kan inmeng met aktiwiteite wat verstandelike helderheid vereis. Pasiënte moet dus aangeraai word om nie 'n voertuig te bestuur of met masjinerie te werk nie, totdat individuele vatbaarheid bekend is.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN:
Daar is geen spesifieke teenmiddel vir oordosering van QUETIAPINE BIOTECH nie. Behandeling is simptomaties en ondersteunend.
Oor die algemeen is tekens en simptome wat aangemeld is, dié wat uitgespruit het uit 'n verergering van quetiapine se bekende farmakologiese effekte, m.a.w. slaaperigheid en sedasie, tagikardie en hipotensie.
Pasiënte met ernstige voorafbestaande kardiovaskulêre siekte kan 'n verhoogde risiko van oordosering hê.

IDENTIFIKASIE:
QUETIAPINE BIOTECH 25: Ronde, bikonvekse, pienk film-bedekte tablet
QUETIAPINE BIOTECH 100: Ronde, bikonvekse, geel film-bedekte tablet
QUETIAPINE BIOTECH 200: Ronde, bikonvekse, wit film-bedekte tablet
QUETIAPINE BIOTECH 300: Langwerpige, bikonvekse, wit film-bedekte tablet

AANBIEDING:
30; 60; 90 of 100 Tablette word verpak in Poliamied/Aluminium/PVC stulpstroke of PVC/Aluminium en aluminium stroke. Elke stulpstrook bevat tien tablette. Die stulpstroke word verpak in 'n buitenste kartonhouer.

BERGINGSINSTRUKSIES:
Bewaar teen of benede 25 ˚C. Hou die stulpstroke in die buitenste kartonhouer tot benodig word vir gebruik.
HOU BUITE BEREIK VAN KINDERS

REGISTRASIE NOMMERS
QUETIAPINE BIOTECH 25 (Film-bedekte Tablet) : 45/2.6.5/0212
QUETIAPINE BIOTECH 100 (Film-bedekte Tablet) : 45/2.6.5/0213
QUETIAPINE BIOTECH 200 (Film-bedekte Tablet) : 45/2.6.5/0214
QUETIAPINE BIOTECH 300 (Film-bedekte Tablet) : 45/2.6.5/0215

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
BIOTECH LABORATORIES (EDMS) BPK.
Grond Vloer, Blok K Wes, Central Park
400 16de Weg, Randjespark, Midrand, 1685
Suik Afrika

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
Datum van Registrasie: 31 July 2014
Datum van die jongste hersiening van die teks; soos deur die Raad goedgekeur: 31 July 2014
Datum van kennisgewing met betrekking tot gewysigde Regulasie 9 & 10: 6 May 2016