Pharmacode position may change as per Supplier's m/c requirement & additional small pharma code may appear on the front / back panel

APPROVED
Samantha , 2023/02/17 ,07:49:01

P1533304
QUETZ 25MG TABLETS

QUETZ TABLETS
P1533304

PROFESSIONAL INFORMATION FOR HUMAN USE
SCHEDULING STATUS

S5

PROPRIETARY NAME (and dosage form)
QUETZ 25 mg (tablet)
QUETZ 100 mg (tablet)
QUETZ 200 mg (tablet)
QUETZ 300 mg (tablet)

COMPOSITION:
QUETZ 25 mg : Each film-coated tablet contains quetiapine fumarate equivalent to quetiapine 25 mg. Contains sugar: 5,167 mg lactose
QUETZ 100 mg: Each film-coated tablet contains quetiapine fumarate equivalent to quetiapine100 mg. . Contains sugar: 20,667 mg lactose
QUETZ 200 mg: Each film-coated tablet contains quetiapine fumarate equivalent to quetiapine 200 mg. Contains sugar: 41,333 mg lactose
QUETZ 300 mg: Each film-coated tablet contains quetiapine fumarate equivalent to quetiapine 300 mg. Contains sugar: 62,000 mg lactose.

The other ingredients of **QUETZ** are calcium hydrogen phosphate; cellulose microcrystalline; lactose; magnesium stearate; povidone; silica colloidal anhydrous; sodium starch glycolate and talc.

The coating material of **QUETZ 25 mg** contains hypromellose; iron oxide red(C.I. No: 77491); iron oxide yellow (C.I. No: 77492); macrogol / PEG 400 and titanium dioxide (C.I. No: 77891).The coating material of **QUETZ 100 mg** contains hypromellose; iron oxide yellow (C.I. No: 77492); macrogol / PEG 400 and titanium dioxide (C.I. No: 77891).The coating material of **QUETZ 200 mg** contains hypromellose; macrogol 400and titanium dioxide (C.I. No: 77891).The coating material of **QUETZ 300 mg** contains hypromellose; macrogol 400 and titanium dioxide (C.I. No: 77891).The imprinting ingredients used on **QUETZ 100 mg**, **QUETZ 200 mg** and **QUETZ 300 mg** contains ammonium hydroxide; iron oxide black (C.I. No: 77499); isopropyl alcohol; N-butylalcohol; propylene glycol and shellac glaze in ethanol.

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

PHARMACOLOGICAL ACTION
Pharmacodynamic properties:
Quetiapine is an atypical antipsychotic agent which interacts with a broad range of neurotransmitter receptors. Quetiapine exhibits a higher affinity for serotonin (5-HT2) receptors in the brain than it does for dopamine D1 and D2 receptors in the brain. Quetiapine also has high affinity at histaminergic and adrenergic alpha-1 receptors, with a lower affinity at adrenergic alpha-2 receptors, but no appreciable affinity at benzodiazepine or cholinergic muscarinic receptors. Quetiapine is active in tests for antipsychotic activity, such as conditioned avoidance, in animal models. In man, quetiapine does not produce sustained elevations in prolactin. Quetiapine, when given twice a day, maintains 5-HT2 and D2 receptor occupancy for up to 12 hours after dosing.

Pharmacokinetic properties:
Following oral administration, quetiapine is absorbed and extensively metabolised. The principal human plasma metabolites do not have significant pharmacological activity. Administration with food does not significantly affect the bioavailability of quetiapine. The elimination half-life of quetiapine is approximately 7 hours. Quetiapine is approximately 65 % - 83 % bound to plasma proteins.

The pharmacokinetics of quetiapine are variable but do not differ significantly between women and men. In the elderly, the mean clearance of quetiapine is approximately 30 % - 50 % lower than that seen in adults aged 18 - 65 years. The mean plasma 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

Quetiapine is extensively metabolised with the parent compound accounting for less than 5 % of unchanged medicine-related material in the urine or faeces, following the administration of radio-labelled quetiapine. Approximately 73 % of the radioactivity is excreted in the urine and 21 % in the faeces.

CYP3A4 is the primary enzyme responsible for cytochrome P450 mediated metabolism of quetiapine.

Quetiapine and several of its metabolites were found to be weak inhibitors of human cytochrome P450 1A2, 2C9, 2C19, 2D6 and 3A4 activities, but only at concentrations of at least 10 - 50 fold higher than those observed in the usual effective dose range of 300 to 450 mg/day in humans.

INDICATIONS
QUETZ is indicated for the treatment of schizophrenia.

QUETZ is also indicated for the treatment of manic episodes associated with a bipolar disorder. Safety and efficacy beyond 12weeks has not been established.

CONTRA-INDICATIONS
Hypersensitivity to quetiapine or to any of the other ingredients of QUETZ. Pregnancy and lactation, since safety has not been established. Safety and efficacy in children and adolescents have not been established. Advanced liver and renal function impairment, since safety has not been established.

WARNINGS AND SPECIAL PRECAUTIONS
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 medicine in inducing such behaviour has not been established.

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

If the decision is made to discontinue treatment, **QUETZ** should be tapered (See "**DOSAGE AND DIRECTIONS FOR USE**").

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 atypical antipsychotics including **QUETZ.**

Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics such as **QUETZ,** 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 such as **QUETZ** should be monitored for symptoms of hyperglycaemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycaemia during treatment with atypical antipsychotics such as **QUETZ,** should undergo fasting blood glucose testing. In some cases, hyperglycaemia has resolved when the atypical antipsychotic such as **QUETZ,** was discontinued; however, some patients required continuation of antidiabetic treatment despite discontinuation of the suspect medicines. Somnolence may occur, usually during the first 2 weeks of treatment and generally resolves with the continued administration of **QUETZ**. Resolution of leukopenia and/or neutropenia usually follows cessation of therapy with **QUETZ**. Possible risk factors for leukopenia and/or neutropenia include pre-existing low white cell count and history of medicine induced leukopenia and/or neutropenia. Agranulocytosis has been reported in patients on treatment with quetiapine. Although a causal relationship could not be established, the possibility that **QUETZ** may be implicated could not be excluded.

Concomitant illness:
QUETZ should be used with caution in patients with mild to moderate hepatic or renal impairment, with known cerebrovascular disease, cardiovascular disease or other conditions predisposing to hypotension, or with a history of seizures. **QUETZ** may induce orthostatic hypotension, especially during the initial dose-titration period; this is more common in elderly patients than in younger patients. Quetiapine as in **QUETZ** has not been associated with a persistent increase in QTc intervals. However, caution should be exercised when **QUETZ** is prescribed with medicines known to prolong the QTc interval, especially in the elderly.

Seizures:
When treating patients with a history of seizures, caution is recommended.

Tardive dyskinesia:
There is a potential for **QUETZ** to cause tardive dyskinesia. If signs and symptoms of tardive dyskinesia appear, discontinuation of **QUETZ** should be considered.

Neuroleptic malignant syndrome:
Neuroleptic malignant syndrome has been associated with **QUETZ** treatment. Clinical manifestations include hyperthermia, altered mental status, muscular rigidity, autonomic instability, and increased creatine phosphokinase.

In such an event, **QUETZ** should be discontinued and appropriate medical treatment given. QUETZ contains lactose. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption should not take **QUETZ.**

Effects on ability to drive and use machines:
QUETZ may cause somnolence which may interfere with activities requiring mental alertness. Therefore, until individual susceptibility is known, patients should be advised not to drive or operate machinery.

INTERACTIONS
Because of the primary central nervous system effects of **QUETZ**, **QUETZ** should be used with caution in combination with other centrally acting medicines and alcohol.

The pharmacokinetics of lithium are not altered when co-administered with QUETZ. When co-administered, the pharmacokinetics of sodium valproate and **QUETZ** are not altered to a clinically relevant extent.

The pharmacokinetics of **QUETZ** are not significantly altered following co-administration with the antipsychotics risperidone or haloperidol. However, co-administration of QUETZ and thioridazine may cause increases in clearance of **QUETZ.**

QUETZ does not induce the hepatic enzymes involved in the metabolism of quetiapine. Enzyme inducers such as carbamazepine may decrease the plasma concentrations of quetiapine, and higher doses of **QUETZ** may be necessary.

Co-administration of **QUETZ** with another microsomal enzyme inducer, phenytoin, may also cause increases in clearance of **QUETZ.** Increased doses of **QUETZ** may be required to maintain control of psychotic symptoms in patients co-administered **QUETZ** and phenytoin and other hepatic enzyme inducers (e.g. rifampicin, barbiturates, etc.) The dose of **QUETZ** 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).

CYP3A4 is the primary enzyme responsible for cytochrome P450 mediated metabolism of **QUETZ.**

The pharmacokinetics of **QUETZ** is not altered by co-administration with cimetidine a known P450 enzyme inhibitor. The pharmacokinetics of **QUETZ** are not significantly altered following co-administration with the antidepressants imipramine (a known CYP2D6 inhibitor) or fluoxetine (a known CYP3A4 and CYP2D6 inhibitor).

CYP3A4 is the main isoenzyme responsible for cytochrome P450 mediated metabolism of quetiapine and caution is advised when **QUETZ** is used with potent inhibitors of CYP3A4 such as macrolide antibiotics (e.g. erythromycin) and azole antifungals (e.g. fluconazole, itraconazole, and ketoconazole); lower doses of **QUETZ** should be used when given with such inhibitors. **QUETZ** should be used with caution in patients also receiving antihypertensives or medicines that prolong the QT interval. **QUETZ** may antagonise the actions of dopaminergics such as levodopa.

PREGNANCY AND LACTATION
QUETZ is contra-indicated during pregnancy and lactation, since safety has not been established.

DOSAGE AND DIRECTIONS FOR USE
QUETZ should be administered twice daily, with or without food.

Adults:
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.

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 in 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.

It should be noted that the recommended maximum daily dose of **QUETZ** is 750 mg/day, for the treatment of schizophrenia, and 800 mg/day for the treatment of manic episodes associated with bipolar disorder. Continued treatment at higher doses should only be considered as a result of careful consideration of the benefit-risk assessment for an individual patient.

Elderly:
QUETZ should be used with caution in the elderly, especially during the initial dosing period. Elderly patients should be started on **QUETZ** 25 mg/day. The dose should be increased daily, in increments of 25 - 50 mg, to an effective dose, which is likely to be lower than that in younger patients.

Renal and hepatic impairment:
In patients with mild to moderate renal or hepatic impairment, the oral clearance of **QUETZ** is reduced by approximately 25 %. **QUETZ** is extensively metabolised by the liver. Therefore, caution should be exercised when administered to patients with known hepatic impairment. Patients with renal or hepatic impairment should be started on **QUETZ** 25 mg/day. The dose should be increased daily, in increments of 25 - 50 mg, to an effective dose.

SIDE-EFFECTS
The following side-effects have been reported.

Blood and lymphatic system disorders:
Frequent:
Leucopenia
Less frequent:
Eosinophilia, neutropenia

Immune system disorders:
Less frequent:
Hypersensitivity (angioedema, anaphylaxis, urticaria/rash)

Endocrine disorders:
Less frequent:
Treatment with quetiapine is associated with dose-related decreases in thyroid hormone levels, particularly total T4 and free T4. The reduction in total and free T4 was maximal within the first 2 to 4 weeks of **QUETZ** treatment.
Frequency not known:
Rises in prolactin concentrations

Metabolism and nutrition disorders:
Less frequent:
Anorexia

Nervous system disorders:
Frequent:
Dizziness, somnolence, syncope
Less frequent:
Seizure, dysarthria, hypertonia, extrapyramidal symptoms (akathisia, akinesia, cogwheel rigidity, extrapyramidal syndrome, hypertonia, hypokinesia, neck rigidity and tremor) occur and are not dose related.
Frequency not known:
Anxiety

Eye disorders:
Less frequent:
Asymptomatic changes in the lens of the eye may occur in patients during long-term treatment with **QUETZ**.
Abnormal vision
Frequency not known:
Dry eyes

Ear and labyrinth disorders:
Frequency not known:
Ear pain

Cardiac disorders:
Frequent:
Tachycardia
Less frequent:
Palpitation, prolongation of the QTc interval

Vascular disorders:
Less frequent:
Hypotension, orthostatic hypotension
Frequency not known:
Hypertension

Respiratory, thoracic and mediastinal disorders:
Less frequent:
Dyspnoea, pharyngitis, rhinitis

Gastrointestinal disorders:
Less frequent:
Abdominal pain
Frequency not known:
Diarrhoea, dry mouth, constipation, dyspepsia

Skin and subcutaneous tissue disorders:
Less frequent:
Increased sweating

Musculoskeletal, connective tissue and bone disorders:
Frequency not known:
Myalgia

Renal and urinary disorders:
Frequency not known:
Urinary tract infection

Reproductive system and breast disorders:
Less frequent:
Menstrual changes, galactorrhoea
Rare:
Priapism

General disorders and administrative site conditions:
Frequent:
Asthenia, peripheral oedema
Less frequent:
Headache, flu-like symptoms, fever
Frequency not known:
Back pain, chest pain
Rare:
Neuroleptic malignant syndrome

Investigations:
Frequent:
Weight gain, elevations in serum transaminases (ALT, AST)
Less frequent:
Elevations in gamma-GT levels, elevations in non-fasting serum triglyceride

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
There have been less frequent reports of overdose of quetiapine alone resulting in death or coma.

In general, reported signs and symptoms were those resulting from an exaggeration of the medicine's known pharmacological effects, i.e., drowsiness, sedation, tachycardia and hypotension.

There is no specific antidote to **QUETZ**. Treatment is symptomatic and supportive.

IDENTIFICATION
QUETZ 25 mg:
Peach, round, biconvex, film-coated tablets debossed with 'E 52' on one side and plain on the other side.

QUETZ 100 mg:
Yellow, round, biconvex, film-coated tablets imprinted with 'E 53' on one side and plain on the other side.

QUETZ 200 mg:
White, round, biconvex, film-coated tablets imprinted with 'E 55' on one side and plain on the other side.

QUETZ 300 mg:
White, capsule shaped, biconvex, film-coated tablets imprinted with 'E 56' on one side and plain on the other side.

PRESENTATION
QUETZ 25 mg:
Blister Pack:
Tablets are packed in white opaque 250 micron PVC film and printed 25 micron aluminium foil with 7 gsm heat seal lacquer. Each blister contains 10 tablets.
Pack sizes: 30's – Each carton contains 3 blisters of 10 tablets each.
90's – Each carton contains 9 blisters of 10 tablets each.
100's – Each carton contains 10 blisters of 10 tablets each.

HDPE Container Pack:
Tablets are packed in 40 ml white opaque HDPE container of 33 mm neck finish with 33 mm–400 RS white opaque closure, with TEKNIPLEX HS-123 induction sealing wad.
Pack sizes: 30's – One HDPE container contains 30 tablets.
90's - One HDPE container contains 90 tablets.

QUETZ 100 mg:
Blister Pack:
Tablets are packed in white opaque 250 micron PVC film and printed 25 micron aluminium foil with 7 gsm heat seal lacquer. Each blister contains 10 tablets.
Pack size: 90's – Each carton contains 9 blisters of 10 tablets each.
HDPE Container Pack:
Tablets are packed in 40 ml white opaque HDPE container of 33 mm neck finish with 33 mm–400 RS white opaque closure, with TEKNIPLEX HS-123 induction sealing wad.
Pack size: 90's - One HDPE container contains 90 tablets.

QUETZ 200 mg:
Blister Pack:
Tablets are packed in white opaque 250 micron PVC film and printed 25 micron aluminium foil with 7 gsm heat seal lacquer. Each blister contains 10 tablets.

Pack size: 30's – Each carton contains 3 blisters of 10 tablets each.
60's – Each carton contains 6 blisters of 10 tablets each.

HDPE Container Pack:
Tablets are packed in 40 ml white opaque HDPE container of 33 mm neck finish with 33 mm–400 RS white opaque closure with TEKNIPLEX HS-123 induction sealing wad.
Pack size: 30's - One HDPE container contains 30 tablets.

QUETZ 300 mg:
Blister Pack:
Tablets are packed in white opaque PVC film and printed aluminium foil. Each blister contains 10 tablets.
Pack size: 30's – Each carton contains 3 blisters of 10 tablets each.
60's – Each carton contains 6 blisters of 10 tablets each.

HDPE Container Pack:
Tablets are packed in 40 ml white opaque HDPE container with white opaque closure, with induction sealing wad.
Pack size: 30's - One HDPE container contains 30 tablets.

STORAGE INSTRUCTIONS
Store at or below 30 °C.
Do not remove the blisters from the carton until required. Keep the containers tightly closed.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
QUETZ 25 mg: 45/2.6.5/0646
QUETZ 100 mg: 45/2.6.5/0647
QUETZ 200 mg: 45/2.6.5/0648
QUETZ 300 mg: 45/2.6.5/0649

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
AUROGEN SOUTH AFRICA (PTY) LTD
Woodhill Office Park, Building 1, First Floor
53 Phillip Engelbrecht Avenue
Meyersdal Ext 12, 1448
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MARKETED BY:
ZYDUS HEALTHCARE SA (PTY) LTD
Southdowns Office Park
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South Africa

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16/02/2023

PATIENT INFORMATION LEAFLET

S5

QUETZ 25 mg (tablet)
QUETZ 100 mg (tablet)
QUETZ 200 mg (tablet)
QUETZ 300 mg (tablet)

Quetiapine fumarate

Read all of this leaflet carefully before you start taking QUETZ.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **QUETZ** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT QUETZ CONTAINS
The active substance is quetiapine.

QUETZ 25 mg:
Each film-coated tablet contains quetiapine fumarate equivalent to quetiapine 25 mg. Contains sugar: 5,167 mg lactose.

QUETZ 100 mg:
Each film-coated tablet contains quetiapine fumarate equivalent to quetiapine 100 mg. Contains sugar: 20,667 mg lactose

QUETZ 200 mg:
Each film-coated tablet contains quetiapine fumarate equivalent to quetiapine 200 mg. Contains sugar: 41,333 mg lactose

QUETZ 300 mg:
Each film-coated tablet contains quetiapine fumarate equivalent to quetiapine 300 mg. Contains sugar: 62,000 mg lactose.

The other ingredients of **QUETZ** are calcium hydrogen phosphate; cellulose microcrystalline; lactose; magnesium stearate; povidone; silica colloidal anhydrous; sodium starch glycolate and talc. The coating material of **QUETZ 25 mg** contains hypromellose; iron oxide red (C.I. No: 77491); iron oxide yellow (C.I. No: 77492); macrogol / PEG 400 and titanium dioxide (C.I. No: 77891). The coating material of **QUETZ 100 mg** contains hypromellose; iron oxide yellow (C.I. No: 77492); macrogol / PEG 400 and titanium dioxide (C.I. No: 77891). The coating material of **QUETZ 200 mg** contains hypromellose; macrogol 400 and titanium dioxide (C.I. No: 77891). The coating material of **QUETZ 300 mg** contains hypromellose; macrogol 400 and titanium dioxide (C.I. No: 77891). The imprinting ingredients used on **QUETZ 100 mg**,**QUETZ 200 mg** and **QUETZ 300 mg** contains ammonium hydroxide; iron oxide black (C.I. No: 77499); isopropyl alcohol; N-butylalcohol; propylene glycol and shellac glaze in ethanol.

2. WHAT QUETZ IS USED FOR
QUETZ belongs to a group of medicines called anti-psychotics.
QUETZ is used to treat some types of mental illness such as:
- Schizophrenia. Symptoms of schizophrenia include hallucinations (like hearing unexplained voices), strange and frightening thoughts, changes in how you act, and feeling alone and confused.
- Manic episodes that occur with a bipolar disorder. Symptoms of mania include effects on your mood and feeling very "high" or excited. You may feel that you are more than usual. You may also be more talkative and have racing thoughts or ideas. You may also feel more irritable than usual.

3. BEFORE YOU TAKE QUETZ
Do not take QUETZ:
- If you are hypersensitive (allergic) to quetiapine, or any of the other ingredients of **QUETZ**.
- If you are pregnant or breastfeeding.
- In children and adolescents – Because the safety and effectiveness of **QUETZ** has not been determined in this age group.
- If you have advanced liver and kidney problems.

Take special care with QUETZ:
- Before taking **QUETZ**, tell your doctor:
- If you have diabetes or are at risk of getting diabetes (e.g. if you are obese or have a family history of diabetes). If you have diabetes, your doctor will check your blood sugar levels regularly while you are taking **QUETZ**. If you are at risk for getting diabetes, your doctor will monitor you for symptoms of high blood sugar such as excessive thirst and fluid intake, passage of large volume of urine, excessive eating and weakness.
- If you have liver or kidney problems.
- If you have heart problems.
- If you have had a stroke.
- If you have low blood pressure.
- If you have ever had a fit (seizure).
- **QUETZ** may cause lightheadedness or dizziness when getting up from a lying or sitting position, particularly when you first begin treatment. This is more likely to occur in elderly patients. Avoid getting up too fast from a sitting or lying position.
- **QUETZ** may cause a condition called "tardive dyskinesia". Contact your doctor straight away if you develop any of the following symptoms of tardive dyskinesia: uncontrollable movements, mainly of your face or tongue.
- **QUETZ** may cause a condition called "neuroleptic malignant syndrome". Contact your doctor straight away if you develop any of the following symptoms of neuroleptic malignant syndrome: extremely high body temperature, faster breathing, fast heart rate, sweating, stiff muscles, feeling very sleepy or faint, agitation; confusion; tremor (shakes); large increase in blood pressure.
- **QUETZ** may cause a worsening of depression or suicidal thoughts and behaviour whether or not you are taking antidepressant medication. Contact your doctor straight away if you are experiencing this condition.
- If you are taking **QUETZ** your doctor should be monitoring you at the beginning of your treatment or when you experience any changes in your dose to make sure you do not experience worsening of your symptoms or suicidality.

Taking QUETZ with food and drink:
- **QUETZ** can be taken with or without food.
- Be careful how much alcohol you drink. This is because the combined effect of **QUETZ** and alcohol can make you feel sleepy.

Pregnancy and Breastfeeding:
QUETZ must not be taken during pregnancy and breastfeeding. The safe use of **QUETZ** during pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding your baby while taking **QUETZ**, please consult your doctor, pharmacist or other healthcare professional for advice before taking **QUETZ.**

Driving and using machinery:
QUETZ may make you feel sleepy. Do not drive or use any tools or machines until you know how **QUETZ** affects you.

Important information about some of the ingredients of QUETZ
QUETZ contains lactose. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency, or glucose galactose malabsorption should not take **QUETZ.**

Taking other medicines with QUETZ:
Always tell your healthcare professional if you are taking any other medicine.
(This includes complementary or traditional medicines).
- Alcohol.
- Barbiturates (medicines for epilepsy).
- Thioridazine (another anti-psychotic medicine).
- Rifampicin (for tuberculosis).
- Medicines for seizures, such as carbamazepine, phenytoin, phenobarbital or sodium valproate.
- Medicines for depression or mental illness, such as imipramine, haloperidol, risperidone or fluoxetine.
- Erythromycin (an antibiotic medicine)
- Certain antifungal medicines, such as fluconazole, itraconazole and ketoconazole.
- Medicines used to treat high blood pressure.
- Levodopa (for the treatment of Parkinson's disease)
- Medicines known to make the QT interval (a time interval on an ECG ie. electrocardiogram) longer.

If you are using any of these medicines, you may not be able to take **QUETZ**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side-effects.
Before you stop taking any of your medicines, please talk to your doctor first.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of QUETZ with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

4. HOW TO TAKE QUETZ
Always take **QUETZ** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **QUETZ** is too strong or too weak, talk to your doctor or pharmacist
- **QUETZ** should be taken twice a day, with or without food.
- **Adults:**
  - Your doctor will decide on your starting dose and may gradually increase it.
  - After this the dose will usually be between 150 mg and 800 mg each day. It depends on your illness and needs.
- **Elderly people:**
  - If you are elderly your doctor may give you a lower dose.
- **Kidney and liver problems:**
  - If you have kidney and liver problems your doctor may give you a lower dose.

If you take more QUETZ than you should:
The symptoms of overdose include sleepiness, increased rate of heart beat and low blood pressure.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital.

If you forget to take QUETZ:
If you forget to take a dose, take it as soon as you remember. If it is almost time to take the next dose, wait until then. Do not take a double dose to make up for a forgotten dose.

5. POSSIBLE SIDE-EFFECTS
QUETZ can have side-effects.
If any of the following happens, stop taking **QUETZ** and tell your doctor immediately or go the casualty department of your nearest hospital:
- Hives/rash; difficulty breathing; swelling of your face, lips, tongue, or throat.These are all very serious side-effects. If you have them, you have had a serious allergic reaction to **QUETZ**. You may need urgent medical attention or hospitalisation.
- Neuroleptic malignant syndrome. Symptoms of neuroleptic malignant syndrome include: extremely high body temperature, faster breathing, fast heart rate, sweating, stiff muscles, feeling very sleepy or faint, agitation; confusion; tremor (shakes); large increase in blood pressure (manifesting as Symptoms of headache, blurred vision, vomiting and nosebleeds).
- **QUETZ** may cause a condition called "Tardive dyskinesia". Symptoms of tardive dyskinesia include: uncontrollable movements, mainly of your face or tongue.
- Seizures (fits).
- Painful erection of the penis which lasts for hours.
- Changes in vision

Tell your doctor if you notice any of the following side-effects:
- feeling sleepy (this may go away with time, as you keep taking **QUETZ**); dizziness; dry mouth; lack of energy; constipation; increased rate of heart beat; low blood pressure when standing (this may make you feel dizzy or faint); indigestion; weight gain; fainting; swelling of hands and feet due to retained fluid; stuffy nose; fever; lack of appetite; drowsiness; difficulty speaking;
- anxiety; dry eyes; ear pain; rapid irregular action of heartbeat; low blood pressure; high blood pressure; inflammation of the throat; abdominal pain; diarrhoea (frequent or loose watery stools); increased sweating; muscle pain; bladder or kidney infections; irregular menstrual periods; unexpected production of breast milk (galactorrhoea); headache; flu-like symptoms; back pain; chest pain.
- Abnormal muscle movements. These include difficulty starting muscle movements; shaking; feeling restless or muscle stiffness without pain. Some side-effects are only seen when a blood test is taken. These include too few white blood cells, increased number of a certain type of white blood cells in blood, changes in the amount of certain fats (triglycerides and total cholesterol) in the blood, decreases in thyroid hormone, and increases in liver enzymes and increases in the amount of the hormone prolactin in the blood. Tell your doctor if any of the above side-effects are severe, bothersome, do not go away or about any concerns you have while taking **QUETZ**.

Not all side-effects reported for **QUETZ** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **QUETZ** please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF QUETZ
Store at or below 30 °C (room temperature). Do not remove the blister strip from the carton until required for use. Keep the container well closed.

Store all medicines out of the reach and sight of children.

Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF QUETZ
QUETZ 25 mg:
Blister Pack:
Tablets are packed in white opaque PVC film and printed aluminium foil. Each blister contains 10 tablets.
Pack sizes: 30's – Each carton contains 3 blisters of 10 tablets each.
90's – Each carton contains 9 blisters of 10 tablets each.
100's – Each carton contains 10 blisters of 10 tablets each.

HDPE Container Pack:
Tablets are packed in 40 ml white opaque HDPE container with white opaque closure, with induction sealing wad.
Pack sizes: 30's - One HDPE container contains 30 tablets.
90's - One HDPE container contains 90 tablets

QUETZ 100 mg:
Blister Pack:
Tablets are packed in white opaque PVC film and printed aluminium foil. Each blister contains 10 tablets.
Pack size: 90's – Each carton contains 9 blisters of 10 tablets each.

HDPE Container Pack:
Tablets are packed in 40 ml white opaque HDPE container with white opaque closure with induction sealing wad.
Pack size: 90's - One HDPE container contains 90 tablets.

QUETZ 200 mg:
Blister Pack:
Tablets are packed in white opaque PVC film and printed aluminium foil. Each blister contains 10 tablets.

Pack size: 30's – Each carton contains 3 blisters of 10 tablets each.
60's – Each carton contains 6 blisters of 10 tablets each.

HDPE Container Pack:
Tablets are packed in 40 ml white opaque HDPE container with white opaque closure with induction sealing wad.
Pack size: 30's - One HDPE container contains 30 tablets.

8. IDENTIFICATION OF QUETZ
QUETZ 25 mg:
Peach, round, biconvex, film-coated tablets debossed with 'E 52' on one side and plain on the other side.

QUETZ 100 mg:
Yellow, round, biconvex, film-coated tablets imprinted with 'E 53' on one side and plain on the other side.

QUETZ 200 mg:
White, round, biconvex, film-coated tablets imprinted with 'E 55' on one side and plain on the other side.

QUETZ 300 mg:
White, capsule shaped, biconvex, film-coated tablets imprinted with 'E 56' on one side and plain on the other side.

9. REGISTRATION NUMBER
QUETZ 25 mg : 45/2.6.5/0646
QUETZ 100 mg: 45/2.6.5/0647
QUETZ 200 mg: 45/2.6.5/0648
QUETZ 300 mg: 45/2.6.5/0649

10. NAME AND ADDRESS OF REGISTRATION HOLDER
AUROGEN SOUTH AFRICA (PTY) LTD
Woodhill Office Park, Building 1, First Floor
53 Phillip Engelbrecht Avenue
Meyersdal Ext 12, 1448
Johannesburg, South Africa

MARKETED BY:
ZYDUS HEALTHCARE SA (PTY) LTD
Southdowns Office Park
22 Karee Street
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South Africa

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PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK
SKEDULERINGSTATUS

S5

EIENDOMSNAAM (en doseervorm)
QUETZ 25 mg (tablet)
QUETZ 100 mg (tablet)
QUETZ 200 mg (tablet)
QUETZ 300 mg (tablet)

SAMESTELLING

QUETZ 25 mg:

Elke filmbedekte tablet bevat kwetiapienfumaraat ekwivalent aan kwetiapien 25 mg. Bevat suiker: 5,167 mg laktose

QUETZ 100 mg:

Elke filmbedekte tablet bevat kwetiapienfumaraat ekwivalent aan kwetiapien 100 mg. Bevat suiker: 20,667 mg laktose

QUETZ 200 mg:

Elke filmbedekte tablet bevat kwetiapienfumaraat ekwivalent aan kwetiapien 200 mg. Bevat suiker: 41,333 mg laktose

QUETZ 300 mg:

Elke filmbedekte tablet bevat kwetiapienfumaraat ekwivalent aan kwetiapien 300 mg. Bevat suiker: 60,000 mg laktose

Die ander bestanddele van **QUETZ** is kalsiumwaterstof-fosfaat;mikrokristallyne sellulose; laktose; magnesiumstearaat; povidoon; silica kolloïdaal watervry; natriumstyselglikolaat en talk.

Die bedekkingsmateriaal van **QUETZ 25 mg** bevat hipromellose; ysteroksied rooi (C.I. Nr: 77491); ysteroksied geel (C.I. Nr: 77492); makrogol/ PEG 400 entitaandioksied (C.I. Nr: 77891).

Die bedekkingsmateriaal van **QUETZ 100 mg** bevat hipromellose; ysteroksied geel (C.I. Nr: 77492); makrogol/ PEG 400 en titaandioksied (C.I. Nr: 77891).

Die bedekkingsmateriaal van **QUETZ 200 mg** bevat hipromellose; makrogol 400 en titaandioksied (C.I. Nr: 77891).

Die bedekkingsmateriaal van **QUETZ 300 mg** bevat hipromellose; makrogol 400 en titaandioksied (C.I. Nr: 77891).

Die afdruk-bestanddele wat op **QUETZ 100 mg**, **QUETZ 200 mg** en **QUETZ 300 mg** gebruik word, bevat ammoniumhidroksied; ysteroksied swart (C.I. Nr: 77499); isopropielalkohol; N-butielalkohol; propileenglikol en skellak glasuur in etanol.

FARMAKOLOGIESE KLASSIFIKASIE

A 2.6.5 Sentrale senusisteemdepressante: Diverse structure

FARMAKOLOGIESE WERKING

Farmakodinamiese eienskappe:

Kwetiapien in 'n atipiese antipsigotiese middel wat met 'n wye reeks neurotransmittor-reseptore reageer. Kwetiapien openbaar 'n hoër affiniteit vir serotonien(5-HT2)reseptore in die brein as vir dopamien-D1- en D2- reseptore in die brein. Kwetiapien het ook 'n hoë affiniteit by histamienergiese en adrenergiese alfa-1-reseptore, met 'n laer affiniteit by adrenergiese alfa-2-reseptore, maar geen aansienlike affiniteit by bensodiasepien- of cholinergiese muskarieniese reseptore nie. Kwetiapien is aktief in toetse vir antipsigotiese aktiwiteit, soos gekondisioneerde vermyding in dieremodelle.
By die mens, veroorsaak kwetiapien geen volgehoue verhogings van prolaktien nie. Wanneer dit twee keer per dag gegee word, onderhou kwetiapien 5-HT2- en D2- reseptor-besetting vir tot 12 uur na dosering.

Farmakokinetiese eienskappe:

Na orale toediening, word kwetiapien geabsorbeer en ekstensief gemetaboliseer. Die hoof menslike plasmametaboliete het geen beduidende farmakologiese aktiwiteit nie. Toediening saam met kos verander nie die biobeskikbaarheid van kwetiapien beduidend nie.

Die eliminasie halfleeftyd van kwetiapien is ongeveer 7 uur. Ongeveer 65 % - 83 % van kwetiapien is aan plasmaproteïene gebonde. Die farmakokinetika van kwetiapien kan wissel maar verskil nie beduidend tussen vrouens en mans nie.

By bejaardes is die gemiddelde opruiming van kwetiapien ongeveer 30 % - 50 % laer as dié wat by volwassenes van 18 - 65 jaar waargeneem word.

Die gemiddelde plasmaopruiming van kwetiapien was met ongeveer 25 % verminder by proefpersone met ernstige nierinkorting (kreatinienopruiming minder as 30 ml/min/1,73 m^2) en by proefpersone met hepatiese inkorting (stabiele alkoholiese sirrose), maar die individuele opruimingswaardes is egter binne die reikwydte vir normale persone.

Kwetiapien word ekstensief gemetaboliseer en na die toediening van radiogeëtiketteerde kwetiapien was die stamverbinding vir minder as 5 % van die onveranderde medisyne-verwante materiaal in die urine of faeces verantwoordelik. Ongeveer 73 % van die radioaktiwiteit word in die urine en 21 % word in die ontlasting uitgeskei.

CYP3A4 is die primêre ensiem verantwoordelik vir die sitochroom P450-bemiddelde metabolisme van kwetiapien. Daar is gevind dat kwetiapien en verskeie van sy metaboliete swak inhibeerders van menslike sitochroom P450 1A2-, 2C9-, 2C19-, 2D6- en 3A4-aktiwiteit was, maar slegs teen konsentrasies wat ten minste 10 - 50 keer hoër was as dié wat in die gebruiklike effektiewe dosisreikwydte van 300 tot 450 mg/dag by die mens, waargeneem is.

INDIKASIES

QUETZ word aangedui vir die behandeling van skisofrenie.

QUETZ word ook aangedui vir die behandeling van maniese episodes geassosieer met 'n bipolêre versteuring. Veiligheid en doeltreffendheid na 12 weke, is nie vasgestel nie.

KONTRA-INDIKASIES

Hipersensitiwiteit teen kwetiapien of enige van die ander bestanddele van **QUETZ**.

Swangerskap en laktasie, omdat veiligheid nog nie vasgestel is nie. Veiligheid en doeltreffendheid by kinders en adolessente is nie vasgestel nie. Gevorderde inkorting van lewer- en nierfunksie, omdat veiligheid nog nie vasgestel is nie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS

Pasiënte met major depressiewe versteuring, beide volwassenes en kinders, mag verergering van hulle depressie en/of die ontluiking van selfmoordgedagtes en -gedrag ondervind, of hulle antidepressante medisyne neem, al dan nie. Hierdie risiko mag voortduur totdat beduidende remissie voorkom. 'n Oorsaaklike rol vir antidepressante medisyne om sulke gedrag te induseer, is egter nie vasgestel nie.

Pasiënte wat met **QUETZ** behandel word, behoort nogtans versigtig vir kliniese agteruitgang en neiging tot selfmoord, veral aan die begin van 'n terapiekursus of te eniger tyd van dosisveranderings, beide verhogings of verlagings, dopgehou te word.

Weens die moontlikheid van komorbiditeit tussen major depressiewe versteuring en ander psigiatriese en nie-psigiatriese versteurings, behoort dieselfde voorsorgmaatreëls wat toegepas word wanneer pasiënte met major depressiewe versteurings behandel word, ook toegepas word wanneer pasiënte met ander psigiatriese en nie-psigiatriese versteurings behandel word.
Die volgende simptome is aangemeld by pasiënte wat met antidepressante vir major depressiewe versteuring, asook ander aanduidings, beide psigiatries en nie psigiatries, behandel is: angs, agitasie, paniekaanvalle, slaaploosheid, prikkelbaarheid, hostiliteit (aggressie, impulsiwiteit, akatisie, hipomanie en manie). Alhoewel 'n oorsaaklike rol tussen die ontluiking van selfmoordimpulse nog nie vasgestel is nie, behoort oorweging geskenk te word om die terapeutiese regimen te verander, insluitend om **QUETZ** te staak by pasiënte by wie sulke simptome ernstig is, skielik begin, of nie deel van die pasiënt se presenterende simptome was nie.

Indien die besluit geneem word om behandeling te staak, behoort **QUETZ** geleidelik verminder te word (Sien "**DOSIS EN GEBRUIKSAANWYSINGS**").

Hiperglisemie en diabetes mellitus:

Hiperglisemie, in sommige gevalle ernstig en geassosieer met ketoasidose of hiperosmolêre koma of die dood, is aangemeld by pasiënte wat met atipiese antipsigotiese middels, insluitend **QUETZ**, behandel is.

Pasiënte met 'n bevestigde diagnose van diabetes mellitus wat op atipiese antipsigotiese middels soos **QUETZ** begin word, behoort gereeld gemonitor te word vir verergering van glukosebeheer. Pasiënte met risikofaktore vir diabetes mellitus (bv. obesiteit, familiegeskiedenis van diabetes) wat behandeling met atipiese antipsigotiese middels soos **QUETZ** begin, behoort gemonitor te word vir simptome van hiperglisemie insluitend polidipsie,poliurie, polifagie, en swakheid. Pasiënte wat simptome van hiperglisemie ontwikkel tydens behandeling met atipiese antipsigotiese middels soos **QUETZ**, behoort vastende bloedglukosetoetse te ondergaan. In sommige gevalle, het hiperglisemie verdwyn toe die atipiese antipsigotiese middels soos **QUETZ,** gestaak is; sommige pasiënte het egter voortsetting van antidiabetiese behandeling nodig gehad ten spyte van staking van die verdagte medisyne.

Lomerigheid mag voorkom, gewoonlik tydens die eerste 2 weke van behandeling en dit verbeter gewoonlik met volgehoue toediening van **QUETZ**.

Resolusie van leukopenie en/of neutropenie volg gewoonlik na staking van terapie met **QUETZ**. Moontlike risikofaktore vir leukopenie en/of neutropenie sluit in voorafbestaande lae witseltelling en 'n geskiedenis van medisynegeïnduseerde leukopenie en/of neutropenie. Agranulositose is aangemeld by pasiënte wat behandeling met kwetiapien ontvang het. Alhoewel 'n oorsaaklike verwantskap nie vasgestel kon word nie, kan die moontlikheid dat **QUETZ** geïmpliseer was, nie uitgesluit word nie.

Gelyktydige siekte:

QUETZ behoort met omsigtigheid gebruik te word by pasiënte met ligte tot matige hepatiese of renale inkorting, met bekende serebrovaskulêre siekte, kardiovaskulêre siekte of ander toestande wat predisponeer tot hipotensie, of met 'n geskiedenis van aanvalle. **QUETZ** mag ortostatiese hipotensie, veral tydens die aanvanklike dosis-titrasie periode induseer; dit kom meer algemeen voor by bejaarde pasiënte as by jonger pasiënte.

Kwetiapien soos in **QUETZ** is nie met 'n aanhoudende verhoging in QTc-intervalle geassosieer nie. Omsigtigheid behoort egter uitgeoefen te word wanneer **QUETZ** voorgeskryf word met medisyne waar dit bekend is dat hulle die QTc-interval verleng, veral by bejaardes.

Aanvalle:

Wanneer pasiënte met 'n geskiedenis van aanvalle behandel word, word omsigtigheid aanbeveel.

Tardiewe diskinesie:

Daar bestaan die potensiaal dat **QUETZ** tardiewe diskinesie mag veroorsaak. Indien tekens en simptome van tardiewe diskinesie te voorskyn kom, behoort staking van **QUETZ** oorweeg te word.

Neuroleptiese maligne sindroom:

Neuroleptiese maligne sindroom is met behandeling met **QUETZ** geassosieer. Kliniese manifestasies sluit hipertermie, veranderde geestesstatus, spierrigiditeit, outonome onstabiliteit, en verhoogde kreatienfosfokinase in. In so 'n geval, behoort **QUETZ** gestaak, en toepaslike mediese behandeling gegee te word.

QUETZ bevat laktose. Pasiënte met seldsame oorgeërfde probleme van galaktose-intoleransie, die Lapland-laktasegebrek of glukosegalaktosewanabsorpsie behoort nie **QUETZ** te neem nie.

Effekte op die vermoë om te bestuur en masjiene te gebruik:

QUETZ mag lomerigheid veroorsaak wat kan inmeng met aktiwiteite wat geesteswakkerheid verg. Tot individuele vatbaarheid bekend is, moet pasiënte aangeraai word om nie te bestuur of masjiene te gebruik nie.

INTERAKSIES

Weens die primêre sentrale senusisteemeffekte van **QUETZ**, behoort **QUETZ** met omsigtigheid gebruik te word in kombinasie met ander sentraalwerkende medisyne en alkohol.

Die farmakokinetika van litium word nie verander wanneer dit saam met **QUETZ** toegedien word nie.

Wanneer dit gelyktydig toegedien word, word die farmakokinetika van natriumvalproaat en **QUETZ** nie tot 'n klinies relevante mate verander nie. Na gelyktydige toediening saam met die antipsigotiese middels risperidoon of haloperidol, word die farmakokinetika van **QUETZ** nie beduidend verander nie.

Die gelyktydige toediening van **QUETZ** en tioridasien mag egter toenames in die opruiming van **QUETZ** veroorsaak.

QUETZ induseer nie die hepatiese ensiemsisteme wat by die metabolisme van antipirien betrokke is nie.

Ensieminduseerders soos karbamasepien mag die plasmakonsentrasies van kwetiapien verminder en hoër dosisse van **QUETZ** mag nodig wees. Gelyktydige toediening van **QUETZ** saam met 'n ander mikrosomale ensieminduseerder, fenitoïen, mag ook verhogings in die opruiming van **QUETZ** veroorsaak. Verhoogde dosisse van **QUETZ** mag nodig wees om beheer van psigotiese simptome te handhaaf by pasiënte aan wie **QUETZ** en fenitoïen en ander hepatiese ensieminduseerders (bv. rifampisien, barbiturate, ens.) gelyktydig toegedien word. Die dosis **QUETZ** moet moontlik verminder word indien fenitoïen, karbamasepien of ander hepatiese ensieminduseerders onttrek word en met 'n nie-induseerder (bv. natriumvalproaat) vervang word.

CYP3A4 is die primêre ensiem wat verantwoordelik is vir sitochroom P450-bemiddelde metabolisme van **QUETZ**. Die farmakokinetika van **QUETZ** word nie na gelyktydige toediening saam met simetidien, 'n bekende P450-ensieminduseerder, verander nie. Die farmakokinetika van **QUETZ** word nie na gelyktydige toediening saam met die antidepressante imipramien ('n bekende CYP2D6-inhibeerder) of fluoksetien ('n bekende CYP3A4- en CYP2D6-inhibeerder), beduidend verander nie. CYP3A4 is die hoof isoënsiem verantwoordelik vir sitochroom P450-bemiddelde metabolisme van kwetiapien en omsigtigheid word aanbeveel wanneer **QUETZ** saam met potente inhibeerders van CYP3A4 soos makroliede antibiotika (bv. eritromisien) en asool-antifungale middels (bv. flukonasool, itrakonasool en ketokonasool) gebruik word; laer dosisse van **QUETZ** behoort gebruik te word, as dit saam met sulke inhibeerders gegee word.

QUETZ behoort met omsigtigheid gebruik te word by pasiënte wat ook antihipertensiewe middels of medisyne wat die QT-interval verleng, ontvang.

QUETZ mag die werking van dopamienergiese middels soos levodopa antagoniseer.

SWANGERSKAP EN LAKTASIE

QUETZ is teenaangedui tydens swangerskap en laktasie, omdat veiligheid nog nie vasgestel is nie.

DOSIS EN GEBRUIKSAANWYSINGS

QUETZ behoort twee keer daagliks, met of sonder kos, toegedien te word.

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).

Vanaf Dag 4 en daarna behoort die dosis getitreer te word na die effektiewe dosisreikwydte van 300 - 450 mg/dag. Dit mag egter aangepas word afhangende van die kliniese reaksie en verdraagsaamheid van die individuele pasiënt binne die reikwydte van 150 - 750 mg/dag.

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). Addisionele dosisaanpassings tot by 800 mg/dag teen Dag 6 behoort in inkremente van nie meer as 200 mg/dag, gemaak word.

Die dosis kan aangepas word afhangende van die kliniese reaksie en verdraagsaamheid van die individuele pasiënt binne die reikwydte van 200 - 800 mg/dag. Die gebruiklike effektiewe dosis is in die reikwydte van 400 - 800 mg/dag.

Daar moet opgelet word dat die aanbevole maksimum daaglikse dosis **QUETZ** 750 mg/dag is vir die behandeling van skisofrenie, en 800 mg/dag vir die behandeling van maniese episodes geassosieer met bipolêre versteuring. Voortgesette behandeling teen hoër dosisse behoort alleenlik oorweeg te word na versigtige bepaling van die voordeel-risiko-verhouding vir 'n individuele pasiënt.

Bejaardes:

QUETZ behoort met omsigtigheid by bejaardes gebruik te word, veral gedurende die aanvanklike doseringsperiode. Bejaarde pasiënte behoort op **QUETZ** 25 mg/dag begin te word. Die dosis behoort daagliks verhoog te word in inkremente van 25 - 50 mg tot 'n effektiewe dosis, wat waarskynlik laer sal wees as dié van jonger pasiënte.

Renale en hepatiese inkorting:

By pasiënte met ligte tot matige renale of hepatiese inkorting, is die orale opruiming van **QUETZ** met ongeveer 25 % verminder. **QUETZ** word ekstensief deur die lewer gemetaboliseer. Omsigtigheid behoort dus toegepas te word wanneer dit aan pasiënte met bekende hepatiese inkorting toegedien word.

Pasiënte met renale of hepatiese inkorting behoort met **QUETZ** 25 mg/dag begin te word.

Die dosis behoort daagliks in inkremente van 25 - 50 mg, tot 'n effektiewe dosis,verhoog te word.

NEWE-EFFEKTE

Die volgende newe-effekte is aangemeld.

Bloed- en limfatiese sisteemversteurings:

Frekwent:

Leukopenie

Minder frekwent:

Eosinofilie, neutropenie

Immuunsisteemversteurings:

Minder frekwent:

Hipersensitiwiteit (angio-edeem, anafilakse, urtikarie/ veluitslag)

Endokriene versteurings:

Minder frekwent:

Behandeling met kwetiapien word geassosieer met dosis-verwante verminderings in tiroïedhormoonvlakke, veral totale T4 en vrye T4. Die verlaging in totale en vrye T4 was maksimaal binne die eerste 2 tot 4 weke van **QUETZ-**behandeling.

Frekwensie onbekend:

Verhogings in prolaktienkonsentrasies

Metabolisme en voedingversteurings:

Minder frekwent:

Anoreksie

Senusisteemversteurings:

Frekwent:

Duiseligheid, lomerigheid, sinkopee

Minder frekwent

Aanval, disartrie, hipertonie, ekstrapiramidale simptome (akatisie, akinesie, tandratrigiditeit, ekstrapiramidale sindroom, hipertonie, hipokinesie, nekrigiditeit en tremor) kom voor en is nie dosisverwant nie.

Frekwensie onbekend:

Angs

Oogversteurings:

Minder frekwent:

Asimptomatiese veranderings in die lens van die oog mag voorkom by pasiënte op langtermyn behandeling met **QUETZ**.

Abnormale visie

Frekwensie onbekend:

Droë oë

Oor- en doolhofversteurings:

Frekwensie onbekend:

Oorpyn

Kardiale versteurings:

Frekwent:

Tagikardie

Minder frekwent:

Hartkloppings, verlenging van die QTc-interval

Vaskulêre versteurings:

Minder frekwent:

Hipotensie, ortostatiese hipotensie

Frekwensie onbekend:

Hipertensie

Respiratoriese, torakale en mediastinale versteurings:

Minder frekwent:

Dispnee, faringitis, rinitis

Gastroïntestinale versteurings:

Minder frekwent:

Abdominale pyn

Frekwensie onbekend:

Diarree, droë mond, hardlywigheid, dispepsie

Vel- en onderhuidse weefselversteurings:

Minder frekwent:

Toename in sweet

Muskuloskeletale, bindweefsel- en beenversteurings:

Frekwensie onbekend:

Mialgie

Renale en urinêre versteurings:

Frekwensie onbekend:

Urienweginfeksies

Voortplantingsisteem- en borsversteurings:

Minder frekwent:

Menstruele veranderings, galaktoree

Seldsaam:

Priapisme

Algemene versteurings en toestande by die toedieningsplek:

Frekwent:

Astenie, perifere edeem

Minder frekwent: Hoofpyn, griepagtige simptome, koors

Frekwensie onbekend:

Rugpyn, borspyn

Seldsaam:

Neuroleptiese maligne sindroom

Ondersoeke:

Frekwent:

Gewigstoename, verhogings in serumtransaminases (ALT, AST)

Minder frekwent:

Verhogings in gamma-GT-vlakke, verhogings in nie-vastende serumtrigliseried

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Berigte van oordosis van kwetiapien alleen wat sterfte of koma veroorsaak het,het minder dikwels oorgekom.
Algemeen gesproke was die aangemelde tekens en simptome dit wat voortgespruit het van 'n oorbeklemtoning van die medisyne se bekendefarmakologiese effekte, d.i. lomerigheid, kalmering, tagikardie en hipotensie.
Daar is geen spesifieke teenmiddel vir **QUETZ** nie. Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE

QUETZ 25 mg:

Perskekleurige, ronde, bikonvekse, filmbedekte tablette gedebosseleer met 'E 52' op die een kant en onversier op die ander kant.

QUETZ 100 mg:

Geel, ronde, bikonvekse, filmbedekte tablette met 'E 53' gedruk op die een kant en onversier op die ander kant.

QUETZ 200 mg:

Wit, ronde, bikonvekse, filmbedekte tablette met 'E 55' gedruk op die een kant en onversier op die ander kant.

QUETZ 300 mg:

Wit, kapsule-vormige, bikonvekse, filmbedekte tablette met 'E 56' gedruk op die een kant en onversier op die ander kant.

AANBIEDING

QUETZ 25 mg:

Stulpverpakking:

Tablette word verpak in wit ondeurskynende 250 mikron PVC film en gedrukte 25 mikron aluminiumfoelie met 7 gvm hitte-seël-vernis. Elke stulpverpakking bevat 10 tablette.

Verpakkingsgroottes: **30s -** Elke kartondoos bevat 3 stulpverpakkings van 10 tablette elk.

90s - Elke kartondoos bevat 9 stulpverpakkings van 10 tablette elk.

100s - Elke kartondoos bevat 10 stulpverpakkings van 10tablette elk.

HDPE-Houer Verpakking:

Tablette word verpak in 40 ml wit, ondeurskynende HDPE-houers met 'n 33 mm nek- afwerking met 'n 33 mm-400 RS wit ondeurskynende sluitstuk en 'n TEKNIPLEX HS-123 induksie seëlvulsel.

Verpakkingsgroottes: **30s** - Een HDPE-houer bevat 30 tablette.

90s - Een HDPE-houer bevat 90 tablette.

QUETZ 100 mg:

Stulpverpakking:

Tablette word verpak in wit ondeurskynende 250 mikron PVC film en gedrukte 25 mikron aluminiumfoelie met 7 gvm hitte-seël-vernis. Elke stulpverpakking bevat 10 tablette.

Verpakkingsgrootte: **90s -** Elke kartondoos bevat 9 stulpverpakkings van 10 tablette elk.

HDPE-Houer Verpakking:

Tablette word verpak in 40 ml wit, ondeurskynende HDPE-houers met 'n 33 mm nek- afwerking met 'n 33 mm-400 RS wit ondeurskynende sluitstuk en 'n TEKNIPLEX HS-123 induksie seëlvulsel.

Verpakkingsgrootte: **90s** - Een HDPE-houer bevat 90 tablette.

QUETZ 200 mg:

Stulpverpakking:

Tablette word verpak in wit ondeurskynende 250 mikron PVC film en gedrukte 25 mikron aluminiumfoelie met 7 gvm hitte-seël-vernis. Elke stulpverpakking bevat 10 tablette.

Verpakkingsgrootte: **30s -** Elke kartondoos bevat 3 stulpverpakkings van 10 tablette elk.

60s - Elke kartondoos bevat 6 stulpverpakkings van 10 tablette elk.

HDPE-Houer Verpakking:

Tablette word verpak in 40 ml wit, ondeurskynende HDPE-houers met 'n 33 mm nek- afwerking met 'n 33 mm-400 RS wit ondeurskynende sluitstuk en 'n TEKNIPLEX HS-123 induksie seëlvulsel.

Verpakkingsgrootte: **30s** - Een HDPE-houer bevat 30 tablette.

QUETZ 300 mg:

Stulpverpakking:

Tablette word verpak in wit ondeurskynende 250 mikron PVC film en gedrukte 25 mikron aluminiumfoelie met 7 gvm hitte-seël-vernis. Elke stulpverpakking bevat 10 tablette.

Verpakkingsgrootte: **30s -** Elke kartondoos bevat 3 stulpverpakkings van 10 tablette elk.

60s - Elke kartondoos bevat 6 stulpverpakkings van 10 tablette elk.

HDPE-Houer Verpakking:

Tablette word verpak in 40 ml wit, ondeurskynende HDPE-houers met 'n 33 mm nek- afwerking met 'n 33 mm-400 RS wit ondeurskynende sluitstuk en 'n TEKNIPLEX HS-123 induksie seëlvulsel.

Verpakkingsgrootte: **30s** - Een HDPE-houer bevat 30 tablette.

BEWARINGSINSTRUKSIES

Bewaar by of benede 30 °C .

Moenie die stulpverpakkings uit die kartondoos verwyder nie totdat dit benodig word. Hou die houers dig gesluit.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER

QUETZ 25 mg : 45/2.6.5/0646
QUETZ 100 mg: 45/2.6.5/0647
QUETZ 200 mg: 45/2.6.5/0648
QUETZ 300 mg: 45/2.6.5/0649

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

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DATUM VAN PUBLIKASIE VAN DIE VOUBILJET

Datum van registrasie:
5 Junie 2014

Datum van hersiening:
6 Desember 2022

P1533304

DETACH BEFORE DISPENSING

PASIËNTINLIGTINGSBROSJURE

S5

QUETZ 25 mg (tablet)
QUETZ 100 mg (tablet)
QUETZ 200 mg (tablet)
QUETZ 300 mg (tablet)

Kwetiapienfumaraat

Lees hierdie hele brosjure versigtig voordat jy begin om QUETZ te neem.
- Hou hierdie brosjure. Jy mag dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter of jou apteker daaroor.
- **QUETZ** is vir jou persoonlik voorgeskryf en jy behoort nie jou medisyne met ander persone te deel nie. Dit kan hulle skade aandoen, al is hulle simptome dieselfde as joune.

1. WAT QUETZ BEVAT

Die aktiewe stof is kwetiapien.

QUETZ 25 mg:

Elke filmbedekte tablet bevat kwetiapienfumaraat ekwivalent aan kwetiapien 25 mg. Bevat suiker: 5,167 mg laktose

QUETZ 100 mg:

Elke filmbedekte tablet bevat kwetiapienfumaraat ekwivalent aan kwetiapien 100 mg. Bevat suiker: 20,667 mg laktose

QUETZ 200 mg:

Elke filmbedekte tablet bevat kwetiapienfumaraat ekwivalent aan kwetiapien 200 mg. Bevat suiker: 41,333 mg laktose

QUETZ 300 mg:

Elke filmbedekte tablet bevat kwetiapienfumaraat ekwivalent aan kwetiapien 300 mg. Bevat suiker: 60,000 mg laktose

Die ander bestanddele van **QUETZ** is kalsiumwaterstof-fosfaat; mikrokristallyne sellulose; laktose; magnesiumstearaat; povidoon; silika kolloïdaal watervry; natriumstyselglikolaat en talk. Die bedekkingsmateriaal van **QUETZ 25 mg** bevat hipromellose;
ysteroksied rooi (C.I. Nr: 77491); ysteroksied geel (C.I. Nr: 77492); makrogol/ PEG 400 en titaandioksied (C.I.Nr: 77891). Die bedekkingsmateriaal van **QUETZ 100 mg** bevat hipromellose; ysteroksied geel (C.I. Nr: 77492); makrogol/ PEG 400 en titaandioksied (C.I. Nr: 77891). Die bedekkingsmateriaal van **QUETZ 200 mg** bevat hipromellose;makrogol 400 en titaandioksied (C.I. Nr: 77891). Die bedekkingsmateriaal van **QUETZ 300 mg** bevat hipromellose; makrogol 400 en titaandioksied (C.I. Nr: 77891).
Die afdruk-bestanddele wat op **QUETZ 100 mg**, **QUETZ 200 mg** en **QUETZ 300 mg** gebruik word, bevat ammoniumhidroksied; ysteroksied swart (C.I. Nr: 77499); isopropielalkohol; N-butielalkohol; propileenglikol en skellak glasuur in etanol.

2. WAARVOOR QUETZ GEBRUIK WORD

QUETZ behoort aan 'n groep medisyne wat antipsigotiese middels genoem word.

QUETZ word gebruik om sommige soorte geestesversteurings te behandel soos:

- Skisofrenie. Simptome van skisofrenie sluit in hallusinasies (soos om stemme te hoor wat nie verduidelik kan word nie), vreemde en skrikwekkende gedagtes, veranderings in jou optrede, en 'n gevoel van eensaamheid en verwarring.
- Maniese episodes wat met 'n bipolêre versteuring voorkom. Simptome van manie sluit in effekte op jou gemoedstoestand en 'n gevoel van groot opgeruimdheid of opwinding. Jy mag voel dat jy minder slaap as gewoonlik nodig het. Jy mag ook meer praat as gewoonlik en vlietende gedagtes en idees hê. Jy mag ook meer prikkelbaar as gewoonlik voel.

3. VOORDAT JY QUETZ NEEM

Moenie QUETZ neem nie:

- Indien jy hipersensitief (allergies) vir kwetiapien, of enige van die ander bestanddele van **QUETZ** is.
- Indien jy swanger is of borsvoed.
- In kinders en adolessente - omdat die veiligheid en doeltreffendheid van **QUETZ** nog nie in hierdie ouderdomsgroep bepaal is nie.
- Indien jy gevorderde lewer- en nierprobleme het.

Neem spesiale sorg met QUETZ:

- Voordat jy **QUETZ** neem, moet jy jou dokter vertel:
- Indien jy diabetes het of aan die risiko om diabetes te ontwikkel blootgestel is (bv. as jy obees is of 'n familiegeskiedenis van diabetes het). Indien jy diabetes het, sal jou dokter jou bloedsuikervlakke gereeld laat toets terwyl jy **QUETZ** neem. Indien jy aan die risiko om diabetes te ontwikkel, blootgestel is, sal jou dokter jou monitor vir simptome van hoë bloedsuiker soos oormatige dors en vloeistofinname, passering van groot volumes urine,oormatige eet en swakheid.
- Indien jy lewer- of nierprobleme het.
- Indien jy hartprobleme het.
- Indien jy 'n beroerte gehad het.
- Indien jy lae bloeddruk het.
- Indien jy al ooit 'n aanval (konvulsie) gehad het.
- **QUETZ** mag lighoofdigheid of duiseligheid veroorsaak wanneer jy uit 'n lêende of sittende posisie opstaan, veral wanneer jy eers met behandeling begin. Dit is meer geneig om by bejaarde pasiënte voor te kom. Vermy te vinnig opstaan uit 'n lêende of sittende posisie.
- **QUETZ** mag 'n toestand veroorsaak wat as "tardiewe diskinesie" bekend staan. Kontak jou dokter dadelik indien jy enige van die volgende simptome van tardiewe diskinesie ontwikkel: onbeheerde bewegings, veral van jou gesig of tong.
- **QUETZ** mag 'n toestand veroorsaak wat as "neuroleptiese maligne sindroom" bekend staan. Kontak jou dokter dadelik indien jy enige van die volgende simptome van neuroleptiese maligne sindroom ontwikkel: uitermatige hoë liggaamstemperatuur, vinniger asemhaling, vinnige harttempo, sweet, stywe spiere, voel baie slaperig of word flou, agitasie, verwarring, tremor (bewerasies), groot toename in bloeddruk.
- **QUETZ** mag verergering van depressie of selfmoordgedagtes en -gedrag veroorsaak of jy antidepressante medikasie neem, al dan nie. Kontak jou dokter dadelik indien jy hierdie toestand ondervind.
- Indien jy **QUETZ** neem, behoort jou dokter jou aan die begin van jou behandeling te monitor of wanneer jy enige veranderings in jou dosis ondervind, om seker te maak dat jy nie verergering van jou simptome of selfmoordneigings ondervind.

Neem van QUETZ saam met kos en drank:

- **QUETZ** kan met, of sonder kos, geneem word.
- Wees versigtig hoeveel alkohol jy drink. Dit is omdat die gekombineerde effek van **QUETZ** en alkohol jou slaperig kan laat voel.

Swangerskap en Borsvoeding:

QUETZ moet nie tydens swangerskap of borsvoeding geneem word nie. Die veilige gebruik van **QUETZ** tydens swangerskap en borsvoeding is nie vasgestel nie.

Indien jy swanger is of jou baba borsvoed terwyl jy **QUETZ** neem, moet jy asseblief jou dokter, apteker of ander gesondheidsorgdeskundige vir advies raadpleeg voordat u **QUETZ** drink.

Bestuur en gebruik van masjiene:

QUETZ kan jou slaperig laat voel. Moenie bestuur of enige gereedskap of masjiene gebruik nie, totdat jy weet hoe **QUETZ** jou affekteer.

Belangrike inligting oor sommige van die bestanddele van QUETZ:

QUETZ bevat laktose. Pasiënte met seldsame oorgeërfde probleme van galaktose-intoleransie, die Lapland-laktasegebrek, of glukose-galaktose-wanabsorpsie behoort nie **QUETZ** te neem nie.

Neem van ander medisyne saam met QUETZ:

Jy moet altyd jou gesondheidsorgdeskundige vertel indien jy enige ander medisyne neem.
(Dit sluit komplementêre of tradisionele medisyne in).

- Alkohol.
- Barbiturate (medisyne vir epilepsie).
- Tioridasien ('n ander antipsigotiese medisyne).
- Rifampisien (vir tuberkulose).
- Medisyne vir aanvalle, soos karbamasepien, fenitoïen, fenobarbital of natriumvalproaat.
- Medisyne vir depressie of geestesversteurings, soos imipramien, haloperidol, risperidoon of fluoksetien.
- Eritromisien ('n antibiotiese medisyne).
- Sekere antifungale medisyne soos flukonasool, itrakonasool en ketokonasool.
- Medisyne wat gebruik word om hoë bloeddruk te behandel.
- Levodopa (vir die behandeling van Parkinson se siekte)
- Medisyne waar dit bekend is dat hulle die QT-interval ('n tydinterval op 'n EKG, d.i. elektrokardiogram) verleng.

Indien jy enige van hierdie medisyne neem, sal jy moontlik **QUETZ** nie kan neem nie, of jy mag moontlik dosisaanpassing benodig, of jou dokter sal jou versigtig moet monitor vir newe-effekte. Voordat jy enige van jou medisyne staak, gesels asseblief eers met jou dokter daaroor.

Indien jy enige medisyne gereeld neem, insluitend komplementêre of tradisionele medisyne, mag die gebruik van **QUETZ** saam met hierdie medisyne ongewenste interaksies veroorsaak. Raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgdeskundige vir advies.

4. HOE OM QUETZ TE NEEM

Neem **QUETZ** altyd presies volgens jou dokter se instruksies. Jy behoort met jou dokter of apteker te gesels indien jy nie seker is nie. Indien jy onder die indruk verkeer dat die effek van **QUETZ** te sterk of te swak is, gesels met jou dokter of apteker daaroor.

- **QUETZ** behoort twee keer per dag, met of sonder kos, geneem te word.
- **Volwassenes:**
  - Jou dokter sal besluit op jou aanvangsdosis en mag dit geleidelik verhoog.
  - Daarna sal hierdie dosis gewoonlik wissel tussen 150 mg en 800 mg elke dag. Dit hang van jou siekte en behoeftes af.
- **Bejaarde persone:**
  - Indien jy bejaard is, sal jou dokter moontlik vir jou 'n laer dosis gee.
- **Nier- en lewerprobleme:**
  - Indien jy nier- en lewerprobleme het, sal jou dokter moontlik vir jou 'n laer dosis gee.

Indien jy meer QUETZ neem as wat jy behoort te neem:

Die simptome van oordosis sluit in slaperigheid, verhoogde hartslagtempo en lae bloeddruk.

In 'n geval van oordosis, raadpleeg jou dokter of apteker. Indien beide nie beskikbaar is nie, moet jy die naaste hospital kontak.

Indien jy vergeet om QUETZ te neem:

Indien jy vergeet om 'n dosis te neem, moet jy dit neem sodra jy daarvan onthou. Indien dit egter amper tyd is vir jou volgende dosis, moet jy tot dan wag. Moenie 'n dubbele dosis neem om op te maak vir 'n vergete dosis nie.

5. MOONTLIKE NEWE-EFFEKTE

QUETZ kan newe-effekte veroorsaak.

Indien jy enige van die volgende simptome ondervind, moet jy **QUETZ** staak en jou dokter vertel of dadelik na die ongevalledepartement van jou naaste hospitaal te gaan:

- Galbulte/ veluitslag; probleme met asemhaling; swelling van jou gesig, lippe, tong of keel. Dit is almal baie ernstige newe-effekte. Indien jy dit het, het jy 'n ernstige allergiese reaksie op **QUETZ**. Jy het moontlik dringende mediese aandag of hospitalisasie nodig.
- Neuroleptiese maligne sindroom. Simptome van neuroleptiese maligne sindroom sluit in: uitermatige hoë liggaamstemperatuur, vinniger asemhaling, vinnige harttempo, sweet, stywe spiere, voel baie slaperig of word flou, agitasie; verwarring; tremor (bewerasies); groot toename in bloeddruk (wat mag manifesteer as simptome sooshoofpyn, versteurde visie, braking en neusbloeding).
- **QUETZ** mag 'n toestand veroorsaak wat "Tardiewe diskinesie" genoem word. Simptome van tardiewe diskinesie sluit in: onbeheerbare bewegings, veral van jou gesig of tong.
- Aanvalle (stuipe)
- Pynlike ereksie van die penis wat vir ure kan duur.
- Veranderings in visie.

Vertel jou dokter indien jy van enige van die volgende newe-effekte bewus word:

- voel lomerig (dit mag met tyd verdwyn, soos jy aanhou om **QUETZ** te neem); duiseligheid, droë mond; gebrek aan energie; hardlywigheid; verhoging in die tempo van die hartslag; lae bloeddruk wanneer jy staan (dit mag jou duiselig of flou laat voel); indigestie; gewigstoename; floute; swelling van die hande en voete as gevolg van vloeistofretensie;toe neus; koors; gebrek aan aptyt; lomerigheid; probleme met praat;
- angs; droë oë; oorpyn; (vinnige onreëlmatige hartklop; lae bloeddruk; hoë bloeddruk; inflammasie van die keel; abdominale pyn; diarree (frekwente of los waterige stoelgang); toename in sweet; spierpyn; blaas- of nierinfeksies; nreëlmatige menstruasie; onverwagte produksie van borsmelk (galaktoree); hoofpyn; griepagtige simptome; rugpyn; borspyn.
- Abnormale spierbewegings. Dit sluit in probleme om met spierbewegings te begin; bewerasies, gevoel van rusteloosheid of spierstyfheid sonder pyn. Sommige newe-effekte word slegs waargeneem wanneer 'n bloedtoets gedoen word. Dit sluit in te min witbloedselle, toename in die getal van sekere soort witbloedselle in die bloed, veranderings in die hoeveelheid van sekere vette (trigliseriede en totale cholesterol) in die bloed, afname in skildklierhormoon, toenames in lewerensieme en toenames in die hoeveelheid prolaktienhormoon in die bloed.

Vertel jou dokter indien enige van bogenoemde newe-effekte ernstig of hinderlik is, nie weggaan nie of oor enigebekommernisse wat jy het terwyl jy **QUETZ** neem.

Nie alle newe-effekte wat vir **QUETZ** aangemeld is, word in hierdie brosjure ingesluit nie. Indien jou algemene gesondheid sou vererger terwyl jy **QUETZ** neem, moet jy asseblief jou dokter, apteker of ander gesondheidsorgdeskundige vir advies raadpleeg.

6. BERGING EN WEGDOENING VAN QUETZ

Bewaar by of benede 30 °C (kamertemperatuur). Moenie die stulpverpakking uit die karton verwyder nie, totdat dit vir gebruik benodig word. Hou die houer dig gesluit.

Bewaar alle medisyne buite bereik en sig van kinders.

Gee alle ongebruikte medisyne terug aan jou apteker. Moenie ongebruikte medisyne in dreine of rioolsisteme (bv. toilette) weggooi nie.

7. AANBIEDING VAN QUETZ

QUETZ 25 mg:

Stulpverpakking:

Tablette word verpak in wit ondeurskynende PVC film en gedrukte aluminiumfoelie. Elke stulpverpakking bevat 10 tablette.

Verpakkingsgroottes: **30s -** Elke kartondoos bevat 3 stulpverpakkings van 10 tablette elk.

90s - Elke kartondoos bevat 9 stulpverpakkings van 10 tablette elk.

100s - Elke kartondoos bevat 10 stulpverpakkings van 10 tablette elk.

HDPE-Houer Verpakking:

Tablette word verpak in 40 ml wit, ondeurskynende HDPE-houers met 'n wit ondeurskynende sluitstuk en 'n induksie seëlvulsel.

Verpakkingsgroottes: **30s** - Een HDPE-houer bevat 30 tablette.

90s - Een HDPE-houer bevat 90 tablette.

QUETZ 100 mg:

Stulpverpakking:

Tablette word verpak in wit ondeurskynende PVC film en gedrukte aluminiumfoelie. Elke stulpverpakking bevat 10 tablette.

Verpakkingsgrootte: **90s -** Elke kartondoos bevat 9 stulpverpakkings van 10 tablette elk.

HDPE-Houer Verpakking:

Tablette word verpak in 40 ml wit, ondeurskynende HDPE-houers met 'n wit ondeurskynende sluitstuk en 'n induksie seëlvulsel.

Verpakkingsgrootte: **90s** - Een HDPE-houer bevat 90 tablette.

QUETZ 200 mg:

Stulpverpakking:

Tablette word verpak in wit ondeurskynende PVC film en gedrukte aluminiumfoelie. Elke stulpverpakking bevat 10 tablette.

Verpakkingsgrootte: **30s -** Elke kartondoos bevat 3 stulpverpakkings van 10 tablette elk.

60s - Elke kartondoos bevat 6 stulpverpakkings van 10 tablette elk.

HDPE-Houer Verpakking:

Tablette word verpak in 40 ml wit, ondeurskynende HDPE-houers met 'n wit ondeurskynende sluitstuk en 'n induksie seëlvulsel.

Verpakkingsgrootte: **30s** - Een HDPE-houer bevat 30 tablette.

QUETZ 300 mg:

Stulpverpakking:

Tablette word verpak in wit ondeurskynende PVC film en gedrukte aluminiumfoelie. Elke stulpverpakking bevat 10 tablette.

Verpakkingsgrootte: **30s -** Elke kartondoos bevat 3 stulpverpakkings van 10 tablette elk.

60s - Elke kartondoos bevat 6 stulpverpakkings van 10 tablette elk.

HDPE-Houer Verpakking:

Tablette word verpak in 40 ml wit, ondeurskynende HDPE-houers met 'n wit ondeurskynende sluitstuk en 'n induksie seëlvulsel.

Verpakkingsgrootte: **30s** - Een HDPE-houer bevat 30 tablette.

8. IDENTIFIKASIE VAN QUETZ

QUETZ 25 mg:

Perskekleurige, ronde, bikonvekse, filmbedekte tablette gedebosseleer met 'E 52' op die een kant en onversier op die ander kant.

QUETZ 100 mg:

Geel, ronde, bikonvekse, filmbedekte tablette met 'E 53' gedruk op die een kant en onversier op die ander kant.

QUETZ 200 mg:

Wit, ronde, bikonvekse, filmbedekte tablette met 'E 55' gedruk op die een kant en onversier op die ander kant.

QUETZ 300 mg:

Wit, kapsule-vormige, bikonvekse, filmbedekte tablette met 'E 56' gedruk op die een kant en onversier op die ander kant.

9. REGISTRASIENOMMER

QUETZ 25 mg: 45/2.6.5/0646
QUETZ 100 mg: 45/2.6.5/0647
QUETZ 200 mg: 45/2.6.5/0648
QUETZ 300 mg: 45/2.6.5/0649

10. NAAM EN ADRES VAN DIE REGISTRASIEHOUER

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