SOUTH AFRICAN PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S5

PROPRIETARY NAME AND DOSAGE FORM

PREXOLAN ODT 5 (orodispersible tablet)

PREXOLAN ODT 10 (orodispersible tablet)

PREXOLAN ODT 15 (orodispersible tablet)

PREXOLAN ODT 20 (orodispersible tablet)

COMPOSITION

Each orodispersible tablet of PREXOLAN ODT 5 contains 5 mg of olanzapine.

Excipients:

Colloidal silicon dioxide, crospovidone, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, mint powder, talc.

Contains sugar:

Lactose monohydrate 60,60 mg

Each orodispersible tablet of PREXOLAN ODT 10 contains 10 mg of olanzapine.

Excipients:

Colloidal silicon dioxide, crospovidone, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, mint powder, talc.

Contains sugar:

Lactose monohydrate 121,20 mg

Each orodispersible tablet of PREXOLAN ODT 15 contains 15 mg of olanzapine.

Excipients:

Colloidal silicon dioxide, crospovidone, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, mint powder, talc.

Contains sugar:

Lactose monohydrate 181,80 mg

Each orodispersible tablet of PREXOLAN ODT 20 contains 20 mg of olanzapine.

Excipients:

Colloidal silicon dioxide, crospovidone, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, mint powder, talc.

Contains sugar:

Lactose monohydrate 242,40 mg

CATEGORY AND CLASS

A 2.6.5 Tranquillisers - miscellaneous structures

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Olanzapine is an atypical antipsychotic medicine having affinity for $5HT_{2A/2C}$, $5HT_3$, $5HT_6$, dopamine D_4, D_3, D_1, D_2, cholinergic muscarinic receptors (m_1 - m_5), ALPHA-1 (α_1) adrenergic and histamine H_1 receptors.

Further studies also demonstrate that olanzapine selectively interacts with the mesolimbic system without significantly interacting with the extrapyramidal system.

Olanzapine's antagonism of muscarinic receptors (m_1 - m_5) may explain its anticholinergic effects. Olanzapine's antagonism of histamine H_1 receptors may explain the somnolence observed with this medicine. Olanzapine's antagonism of adrenergic α_1 receptors may explain the orthostatic hypotension observed with this medicine.

Pharmacokinetic properties

Olanzapine is well absorbed after oral administration, reaching peak plasma concentrations within 5 to 8 hours. The absorption is not affected by food.

Olanzapine is metabolised in the liver by conjugative oxidative pathways. The major circulating metabolite is the 10-N-glucuronide which does not pass the blood-brain barrier. Other metabolites include the N-desmethyl and 2-hydroxymethyl metabolites neither of which has *in-vivo* pharmacological activity. The predominant pharmacologic activity is from the parent compound.

After oral administration the elimination half-life of olanzapine in healthy subjects varies with age and gender.

	< 65 years	≥ 65 years
Men	29 hours	49 hours
Women	39 hours	55 hours

The elimination half-life of olanzapine is about 1,5 times greater in the elderly (≥ 65 years) than in non-elderly subjects (< 65 years) (see WARNINGS AND SPECIAL PRECAUTIONS).

Plasma clearance of olanzapine is higher in smokers (see WARNINGS AND SPECIAL PRECAUTIONS).

The pharmacokinetic characteristics of olanzapine are similar in patients with severe renal impairment and normal subjects, indicating that dosage adjustment based upon the degree of renal impairment is not required. In addition, olanzapine is not removed by haemodialysis. The effect of renal impairment on metabolite elimination has not been studied.

The plasma protein binding of olanzapine is about 93 % over the concentration range of about 7 to about 1 000 ng/ml. Olanzapine is bound predominantly to albumin and α_1-acid-glycoprotein.

INDICATIONS

PREXOLAN ODT is indicated for the management of the manifestations of psychotic disorders.

Effectiveness for more than 6 weeks has not been established in controlled trials. It is recommended that responding patients be continued on PREXOLAN ODT at the lowest dose needed to maintain remission. Patients should be periodically reassessed to determine the need for maintenance treatment.

PREXOLAN ODT is also indicated for the treatment of acute mania in bipolar disorder and for preventing recurrence of manic or depressive episodes of bipolar disorder.

CONTRAINDICATIONS

PREXOLAN ODT is contraindicated in:

- Patients with hypersensitivity to olanzapine or to any components of PREXOLAN ODT.

- Patients with known risk of narrow-angle glaucoma.
- Paediatric patients: safety and effectiveness in patients under 18 years of age has not been established.

WARNINGS AND SPECIAL PRECAUTIONS

Discontinuation reactions

Discontinuation reactions may occur, usually within a week of discontinuing PREXOLAN ODT. These reactions may consist of a cholinergic syndrome (diaphoresis, diarrhoea, sialorrhoea, nausea and vomiting, anxiety, agitation, insomnia and tremor). PREXOLAN ODT should therefore be gradually discontinued.

Acute symptoms such as sweating, insomnia, tremor, anxiety, nausea or vomiting have been reported very rarely when PREXOLAN ODT is stopped abruptly. Gradual dose reduction should be considered when discontinuing therapy.

Hyperprolactinaemia

PREXOLAN ODT elevates prolactin levels and a modest elevation persists during chronic administration. An increase in mammary gland neoplasms has been found in rodents after chronic administration of antipsychotic medicines such as PREXOLAN ODT and is considered to be prolactin mediated. The relevance for human risk of the finding of prolactin mediated endocrine tumours in rodents is unknown.

Neuroleptic malignant syndrome (NMS)

NMS has occurred infrequently in association with PREXOLAN ODT. NMS is a potentially fatal symptom complex. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis and cardiac dysrhythmia). Additional signs may include

elevated creatine phosphokinase, rhabdomyolysis and acute renal failure. PREXOLAN ODT should be discontinued should any of the clinical manifestations of NMS or high fever without additional clinical manifestations of NMS be observed.

Tardive dyskinesia

PREXOLAN ODT is associated with a low incidence of treatment emergent dyskinesia. If signs or symptoms of tardive dyskinesia appear in a patient on PREXOLAN ODT, a dose reduction or discontinuation of treatment should be considered. However, some patients may benefit from continued treatment with PREXOLAN ODT despite the presence of the syndrome. The risk of tardive dyskinesia increases with long-term exposure and symptoms can temporarily deteriorate or even arise after discontinuation of treatment.

Hyperglycaemia and diabetes mellitus

There is an increased prevalence of diabetes amongst patients with schizophrenia. Hyperglycaemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with PREXOLAN ODT. Patients with an established diagnosis of diabetes mellitus who are started on PREXOLAN ODT 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 PREXOLAN ODT should be monitored for symptoms of hyperglycaemia including polydipsia, polyuria, polyphagia and weakness. Patients who develop symptoms of hyperglycaemia during treatment with PREXOLAN ODT should undergo fasting blood glucose testing. In some cases, hyperglycaemia has resolved when PREXOLAN ODT was discontinued. However, some patients required continuation of anti-diabetic treatment despite discontinuation of PREXOLAN ODT.

Seizures

PREXOLAN ODT should be used cautiously in patients who have a history of seizures or who are subject to factors which may lower seizure threshold. Seizures have been reported to occur infrequently in patients treated with PREXOLAN ODT. In most cases, a history of seizures or risk factor for seizures was reported.

Hepatic impairment

Caution should be exercised in patients with signs and symptoms of hepatic impairment, in patients with pre-existing conditions associated with limited hepatic functional reserve and in patients who are being treated with potentially hepatotoxic medicines. Periodic assessment of transaminases is recommended in patients with significant hepatic disease. A starting dose of 5 mg should be considered for patients with moderate hepatic impairment.

Transaminase elevations

Transient elevations of liver transaminases (ALT, AST) have been observed. Caution should therefore be exercised in patients with elevated ALT and/or AST, in patients with signs and symptoms of hepatic impairment, in patients with pre-existing conditions associated with limited hepatic functional reserve and in patients who are being treated with potentially hepatotoxic medicines. In the event of elevated ALT and/or AST during treatment, follow-up should be organised and dose reduction should be considered. In cases when hepatitis has been diagnosed PREXOLAN ODT treatment should be discontinued.

Safety experience in elderly patients with dementia-related psychosis

PREXOLAN ODT is not approved for treatment of patients with dementia-related psychosis. Risk factors that may predispose this patient population to increased mortality when treated with PREXOLAN ODT include age ≥ 80 years, sedation, concomitant use of benzodiazepines, or presence of pulmonary conditions (e.g. pneumonia, with or without aspiration).

Elderly patients

In clinical studies in general there was no indication of any different tolerability of PREXOLAN ODT in the elderly compared to younger adults. Nevertheless, the presence of factors that might decrease pharmacokinetic clearance or increase the pharmacodynamic response to PREXOLAN ODT, should lead to consideration of a lower starting dose.

Orthostatic hypotension

PREXOLAN ODT may induce orthostatic hypotension associated with dizziness, tachycardia and in some patients, syncope, especially during the initial treatment period.

Body temperature regulation

Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic medicines. Appropriate care is advised when prescribing PREXOLAN ODT to patients who will be experiencing conditions which may contribute to an elevation in core body temperature.

Suicide

The possibility of suicide attempt is inherent in schizophrenia and close supervision of high risk patients should accompany PREXOLAN ODT treatment.

Other events observed in patients treated with PREXOLAN ODT in settings other than placebo-controlled clinical trials include a single case of exacerbation of pre-existing intracranial hypertension.

Concomitant illnesses

Clinical experience with PREXOLAN ODT in patients with concomitant illnesses is limited. As PREXOLAN ODT has demonstrated anticholinergic activity *in-vitro* caution is advised when prescribing for patients with symptomatic prostatic enlargement, or paralytic ileus and related conditions.

PREXOLAN ODT has not been evaluated or used to any appreciable extent in patients with a recent history of myocardial infarction or unstable heart disease. Because of the risk of orthostatic hypotension with PREXOLAN ODT, caution should be observed in cardiac patients.

Patients with haematological disorders

Caution should be exercised when using PREXOLAN ODT in patients with low leucocyte and/or neutrophil counts due to any reason, patients with a history of medicine-induced bone marrow depression/toxicity, patients with bone marrow depression caused by concomitant illness, radiation therapy or chemotherapy and in patients with hypereosinophilic conditions or with myeloproliferative disease.

The combined effects of age, smoking and gender could lead to substantial pharmacokinetic differences. The clearance in young smoking males, for example, may be 3 times higher than in elderly non-smoking females. Dosing modification may be necessary in patients who exhibit a combination of factors that may result in slower metabolism of PREXOLAN ODT. Use with caution when concomitantly used with CYP1A2 inducers and inhibitors (see INTERACTIONS).

Dysphagia

Oesophageal dysmotility and aspiration have been associated with antipsychotic medicines. PREXOLAN ODT should be used with caution in patients at risk for aspiration pneumonia.

Cerebrovascular adverse events (CVAE), including stroke, in elderly patients with dementia

Cerebrovascular adverse events (e.g. stroke, transient ischaemia attack), including fatalities, were reported especially in elderly patients with dementia-related psychosis. All patients who experienced a cerebrovascular event had pre-existing risk factors known to be associated with an increased risk for a CVAE (e.g. history of previous CVAE or transient ischaemic

attack, hypertension, cigarette smoking) and presented with concurrent medical conditions and/or concomitant medications having a temporal association with CVAE. PREXOLAN ODT is not approved for the treatment of patients with dementia-related psychosis.

Effects on ability to drive and use machines

PREXOLAN ODT may cause somnolence. Patients should be cautioned about operating hazardous machinery including motor vehicles until they are reasonably certain that PREXOLAN ODT therapy does not affect them adversely.

Excipients

Lactose warning

PREXOLAN ODT contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, the Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take PREXOLAN ODT.

INTERACTIONS

Potential interactions affecting PREXOLAN ODT: Since PREXOLAN ODT is metabolised by CYP1A2, substances that specifically induce, inhibit or act as a substrate to this isoenzyme may affect the pharmacokinetics of PREXOLAN ODT.

Concomitant use of PREXOLAN ODT with:

Other centrally acting medicines - Given the primary CNS effects of PREXOLAN ODT, caution should be exercised when PREXOLAN ODT is taken in combination with other centrally acting medicines (especially those that can cause CNS depression) and alcohol.

Fluoxetine - In combination with PREXOLAN ODT may cause an increase in the maximum

concentration of PREXOLAN ODT and a decrease in PREXOLAN ODT clearance. The effect of repeat dosages and higher dosages of PREXOLAN ODT has not been evaluated. Combination therapy is not advised.

Levodopa - PREXOLAN ODT exhibits *in-vitro* dopamine antagonism and may antagonise the effects of levodopa and dopamine agonists.

Antihypertensive medicines - PREXOLAN ODT may enhance the effects of certain antihypertensive medicines because of the potential for inducing hypotension. PREXOLAN ODT has α_1 adrenergic antagonist activity. Caution should be exercised in patients who receive treatment with medicinal products that can lower blood pressure by mechanisms other than α_1 adrenergic antagonism.

Medicines that increase the QTc interval - Increased QTc interval has been reported. Caution should be exercised when PREXOLAN ODT is prescribed together with other medicines known to increase QTc interval, especially in the elderly, in patients with congenital long QT syndrome, congestive heart failure, heart hypertrophy, hypokalaemia or hypomagnesaemia.

Antacids - Single doses of antacid (aluminium, magnesium) or cimetidine do not affect the oral bioavailability of PREXOLAN ODT. However, the concomitant administration of activated charcoal reduces the oral bioavailability of PREXOLAN ODT by 50 to 60 %. These medicines should be taken at least 2 hours before or after PREXOLAN ODT.

Inducers of CYP1A2 - The metabolism of PREXOLAN ODT may be induced by concomitant smoking or by carbamazepine therapy causing slightly to moderately lower PREXOLAN ODT plasma levels. Clinical monitoring is recommended and an increase of the PREXOLAN ODT dose may be considered if necessary.

Inhibitors of CYP1A2 - Known potent inhibitors of CYP1A2 activity may decrease PREXOLAN ODT clearance. Fluvoxamine, a specific CYP1A2 inhibitor, has been shown to significantly inhibit the metabolism of PREXOLAN ODT. The mean increase in PREXOLAN ODT C_{max} following fluvoxamine is 54 % in female non-smokers and 77 % in male smokers. The mean increase in PREXOLAN ODT AUC was 52 % and 108 % respectively. A lower starting dose of PREXOLAN ODT should be considered in patients who are using fluvoxamine or any other CYP1A2 inhibitors, such as ciprofloxacin or ketoconazole. A decrease in the dose of PREXOLAN ODT should be considered if treatment with an inhibitor of CYP1A2 is initiated.

Potential for PREXOLAN ODT to affect other medicines - No inhibition of the metabolism of imipramine/desipramine (P450-CYP2D6 or P450-CYP3A/1A2), warfarin (P450-CYP2C9), theophylline (P450-CYP1A2) or diazepam (P450-CYP3A4 and P450-CYP2C19) was evident. PREXOLAN ODT does not interact when co-administered with lithium or biperiden.

Studies *in-vitro* using human liver microsomes, determined that PREXOLAN ODT has little potential to inhibit the glucuronidation of valproate, the major metabolic pathway for valproate. Further, valproate was found to have little effect on the metabolism of PREXOLAN ODT *in-vitro*. Daily concomitant *in-vivo* administration of 10 mg PREXOLAN ODT for 2 weeks did not affect steady state plasma concentrations of valproate. Therefore concomitant PREXOLAN ODT administration does not require dosage adjustment of valproate.

HUMAN REPRODUCTION

The safety of PREXOLAN ODT during pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Psychotic disorders: PREXOLAN ODT should be administered on a once a day schedule without regard to meals, beginning with an initial dose of 5 mg to 10 mg per day, with a target dose of 10 mg per day being reached within several days. Further dosage adjustments, if indicated, should occur at intervals of not less than one week.

Acute mania in bipolar disorder: PREXOLAN ODT should be administered on a once a day schedule without regard to meals, generally beginning with 10 mg. Dosage adjustments, within the dose range of 5 mg to 20 mg per day, if indicated, should occur at intervals of not less than 24 hours.

Preventing recurrence in bipolar disorder: The recommended starting dose is 10 mg per day. For patients who have been receiving PREXOLAN ODT for treatment of manic episode, continue therapy for preventing recurrence at the same dose. An increase to a dose greater than the recommended starting dose, within the dose range of 5 mg to 20 mg per day, is advised only after appropriate clinical assessment, and should generally occur at intervals of not less than 24 hours.

A starting dose of 5 mg should be considered for patients with hepatic impairment and may also be considered for the elderly patient.

The safety of doses above 20 mg per day has not been evaluated in clinical trials.

Gradual tapering of the dose should be considered when discontinuing PREXOLAN ODT (see WARNINGS AND SPECIAL PRECAUTIONS).

Improvement in the patient's clinical condition may take several days to weeks.
Patients should be closely monitored during this period.

PREXOLAN ODT should be placed in the mouth, where they will rapidly be dispersed in the saliva so that they can easily be swallowed. You can also place the tablet in a full glass or cup of water and stir. Drink it straight away.

The tablets should not be removed from the blister foil until immediately before administration.

SIDE EFFECTS

Blood and lymphatic system disorders

Frequent: Eosinophilia

Less frequent: Leucopenia, thrombocytopenia, neutropenia

Immune system disorders

Less frequent: Allergic reactions (e.g. anaphylactoid reaction, angioedema, pruritus, urticaria)

Metabolic and nutritional disorders

Frequent: Weight gain, increased appetite

Less frequent: Hyperglycaemia, hypertriglyceridaemia, diabetic ketoacidosis, diabetic coma, elevated cholesterol levels

Frequency unknown: Development or exacerbation of diabetes

Psychiatric disorders

Frequent: Personality disorder, hallucinations

Less frequent: Amnesia, anxiety, euphoria, hostility

Nervous system disorders

Frequent: Somnolence, dizziness, headache, akathisia, Parkinsonism, dyskinesia, asthenia, agitation, abnormal gait, falls, tremor, speech disorders

Less frequent: Articulation impairment, hypertonia, movement disorder, nervousness, myoclonus, insomnia, stuttering, extrapyramidal effects (neck rigidity, muscle spasms of face, neck or back), seizures, dystonia

Frequency unknown: Tardive dyskinesia, neuroleptic malignant syndrome, discontinuation symptoms (sweating, insomnia, tremor, anxiety, nausea and vomiting has been reported when PREXOLAN ODT is stopped abruptly)

Eye disorders

Frequent: Amblyopia

Cardiac disorders

Frequent: Chest pain

Less frequent: Bradycardia, tachycardia, QTc-prolongation

Frequency unknown: Ventricular tachycardia/fibrillation, sudden death

Vascular disorders

Frequent: Orthostatic hypotension, peripheral oedema

Less Frequent: Venous thromboembolism

Respiratory, thoracic and mediastinal disorders

Frequent: Rhinitis, pneumonia

Less frequent: Cough, pharyngitis

Gastrointestinal disorders

Frequent: Dry mouth, constipation

Less frequent: Abdominal pain, pancreatitis

Hepato-biliary disorders

Frequent: Transient asymptomatic elevations of hepatic transaminases (ALT, AST)

Less frequent: Hepatitis

Skin and subcutaneous tissue disorders

Frequent: Rash

Less frequent: Photosensitivity reaction, alopecia

Musculoskeletal, connective tissue and bone disorders

Less frequent: Extremity pain (other than joint), joint pain, rhabdomyolysis

Renal and urinary disorders

Frequent: Urinary incontinence

Less frequent: Urinary hesitation

Reproductive system and breast disorders

Less frequent: Menstrual changes, priapism

General disorders and administration site conditions

Less frequent: Fever, fatigue, oedema

Investigations

Frequent: Elevated prolactin levels, increased ALT, increased AST

Less frequent: High creatine phosphokinase, increased total bilirubin

Frequency unknown: Increased alkaline phosphokinase

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

Frequently occurring symptoms of PREXOLAN ODT overdose (≥ 10 % incidence) include tachycardia, agitation/aggressiveness, dysarthria, various extrapyramidal symptoms and reduced level of consciousness ranging from sedation to coma.

Other medically significant sequelae of PREXOLAN ODT overdose will include delirium, convulsion, possible neuroleptic malignant syndrome, respiratory depression, aspiration, hypertension or hypotension, cardiac dysrhythmias and cardiopulmonary arrest. Fatal outcomes have been reported for acute overdoses as low as 450 mg but survival has also been reported following acute overdose of 1 500 mg.

Treatment

The possibility of multiple medicine involvement should be considered. In case of acute overdosage, establish and maintain an airway and ensure adequate oxygenation and ventilation. Gastric lavage (after intubation, if patient is unconscious) and administration of activated charcoal together with a laxative should be considered. The possibility of obtundation, seizures or dystonic reaction of the head and neck following overdose may create a risk of aspiration with induced emesis. Cardiovascular monitoring should commence immediately and should include continuous electrocardiographic monitoring to detect possible dysrhythmias.

There is no specific antidote to PREXOLAN ODT, therefore appropriate symptomatic and supportive measures should be initiated. Hypotension and circulatory collapse should be

treated with appropriate measures, such as intravenous fluids and/or sympathomimetic medicines. Induction of emesis is not recommended. Do not use epinephrine (adrenaline), dopamine or other sympathomimetics with β-agonist activity, since β-stimulation may worsen hypotension in the setting of PREXOLAN ODT-induced α-blockade. Close medical supervision and monitoring should continue until the patient recovers.

IDENTIFICATION

PREXOLAN ODT 5: Yellow, round, biconvex tablets, with dimensions: 6,0 mm ± 0,1 mm in diameter and thickness 2,6 mm ± 0,2 mm.

PREXOLAN ODT 10: Yellow, round flat tablets, with dimensions: 8,2 mm ± 0,1 mm in diameter and thickness 2,4 mm ± 0,2 mm.

PREXOLAN ODT 15: Yellow, round biconvex tablets, with dimensions: 10,0 mm ± 0,1 mm in diameter and thickness 3,1 mm ± 0,2 mm.

PREXOLAN ODT 20: Yellow, round flat tablets, with dimensions: 11,2 mm ± 0,1 mm in diameter and thickness 2,7 mm ± 0,2 mm.

PRESENTATION

PREXOLAN ODT: 28 or 30 orodispersible tablets are packed in a polyamide/ aluminium/ polyvinyl chloride film and sealed with an aluminium foil backing. There are 7 or 10 tablets per blister strip and one or more blister strips are packed into an outer cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 30 °C.

Protect from light.

Keep the blisters in the carton until required for use.

PREXOLAN ODT should at all times be kept out of reach of children as even small doses may be fatal to them.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

PREXOLAN ODT 5: 44/2.6.5/0915

PREXOLAN ODT 10: 44/2.6.5/0916

PREXOLAN ODT 15: 44/2.6.5/0917

PREXOLAN ODT 20: 44/2.6.5/0918

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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