PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

PROPRIETARY NAME AND DOSAGE FORM

PREXOLAN 2,5

PREXOLAN 5

PREXOLAN 10

Film-coated tablet

Read all of this leaflet carefully before you start taking PREXOLAN.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PREXOLAN 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.

WHAT PREXOLAN CONTAINS

The active substance in PREXOLAN 2,5 is olanzapine 2,5 mg per film-coated tablet.

Contains sugar: Lactose monohydrate 40 mg

The active substance in PREXOLAN 5 is olanzapine 5 mg per film-coated tablet.

Contains sugar: Lactose monohydrate 80 mg

The active substance in PREXOLAN 10 is olanzapine 10 mg per film-coated tablet.

Contains sugar: Lactose monohydrate 160 mg

The other ingredients are crospovidone, hydroxypropyl cellulose, lactose monohydrate, lecithin, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, talc, titanium dioxide (C.I. 77891), xanthan gum.

WHAT PREXOLAN IS USED FOR

PREXOLAN belongs to a group of medicines called antipsychotics.

PREXOLAN is used to treat psychotic conditions which affect the way you think, feel or act (schizophrenia). These conditions may cause symptoms such as hallucinations, delusions, thought disturbances, hostility, suspiciousness, emotional and social withdrawal, reduced emotional expressiveness and poverty of speech (brief and empty replies to questions).

BEFORE YOU TAKE PREXOLAN

Do not take PREXOLAN:

- If you are allergic to PREXOLAN or to any of the ingredients contained in PREXOLAN.
- If you have or likely to have narrow-angle glaucoma (increased pressure in the eye).
- If you are under the age of 18 years. The effects of PREXOLAN have not been tested in children.
- If you are > 80 years of age.

Take special care with PREXOLAN:

- PREXOLAN may cause unusual movements mainly of the face, tongue, lips, trunk, arms and legs. If this happens after you have been given PREXOLAN tell your doctor immediately.
- The use of PREXOLAN in elderly patients with mental deterioration (dementia) is not recommended as it may have serious side effects.
- You should tell your doctor if you suffer from a slow heart beat, if you had a recent heart

attack or uncompensated heart failure (a condition in which the heart can no longer pump enough blood to the rest of the body).

- You should tell your doctor if you smoke.

You should tell your doctor as soon as possible, if you suffer from any of the following illnesses:

- If you have heart problems or have a history of heart disease.
- If you have seizures (fits) as PREXOLAN may increase the risk of seizures (fits).
- If you have liver disease as PREXOLAN may cause liver problems.
- If you have sugar diabetes (high levels of sugar in the blood) or a risk factor for diabetes mellitus (e.g. obesity, family history of diabetes). PREXOLAN may worsen diabetes. Report any symptoms of high blood sugar levels such as increased thirst, increased urination, hunger and weakness to your doctor. Diabetic patients must monitor blood sugar levels more closely while taking PREXOLAN.
- If you are an elderly patient (> 65 years of age).
- If you have prostate problems.
- If you have a blocked intestine (paralytic ileus).
- Uncontrollable movements of mouth, tongue and limbs (tardive dyskinesia).
- Drop in blood pressure when standing up associated with dizziness, faster heart beat and fainting (orthostatic hypotension).
- Disruption of the body's ability to reduce core body temperature (body temperature regulation).
- Cerebrovascular adverse events, including stroke, disturbances of body function lasting for less than 24 hours and caused by localised nervous system defects in the elderly (transient ischaemia attack).
- Difficulty in swallowing (risk of dysphagia).

- Suicide attempt.
- If you are a smoker because the combined effects of age, smoking and gender could lead to slower metabolism of PREXOLAN.
- Increases in the levels of prolactin in the blood (found by blood test).

Taking PREXOLAN with food and drink:

Do not drink any alcohol if you are taking PREXOLAN as PREXOLAN and alcohol together may make you feel drowsy.

The consumption of food does not have an effect on PREXOLAN.

You may take PREXOLAN with or without food.

Pregnancy and Breastfeeding:

You should not take PREXOLAN if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding your baby while taking PREXOLAN, consult your healthcare provider for advice.

Tell your doctor if you are or think that you may be pregnant.

Driving and using machinery:

PREXOLAN may cause drowsiness, trouble in thinking, trouble in controlling movements, or trouble in seeing clearly. Make sure you know how PREXOLAN affects you before you drive, use machines, or do other jobs that require you to be alert, well-coordinated, or able to think or see well.

Important information about some of the ingredients of PREXOLAN:

PREXOLAN tablets contain lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take PREXOLAN. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking PREXOLAN tablets.

Taking other medicines with PREXOLAN:

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

- PREXOLAN may add to the effects of alcohol and other central nervous system (CNS) depressants (medicines that make you drowsy or less alert). Some examples of CNS depressants are antihistamines (medicines for hay fever, other allergies or colds), sedatives (tranquillisers or sleeping medicine), prescription pain medicine or narcotics, barbiturates (medicine for seizures), muscle relaxants, or anaesthetics, including some dental anaesthetics. Check with your doctor before taking any CNS depressants while you are taking PREXOLAN.

You should tell your doctor if:

- You are taking levodopa (normally given to patients suffering from Parkinson's disease).
- You are taking any antihypertensive medication (used for high blood pressure).
- You are taking fluoxetine (an antidepressant).
- You are taking fluvoxamine (an antidepressant), ciprofloxacin (an antibiotic) or ketoconazole (an antifungal) or antacids, as it may be necessary to change your PREXOLAN dose.
- You are taking carbamazepine for epilepsy as it can lower the effect of PREXOLAN.
- You are taking medication that lowers blood pressure.

- You are receiving activated charcoal.
- You are receiving lorazepam injections.

HOW TO TAKE PREXOLAN

Always take PREXOLAN as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Do not share medicines prescribed for you with any other person.

The dose of PREXOLAN will be different for different patients. Follow your doctor's orders. The following information includes only the average doses of PREXOLAN. If your dose is different, do not change it unless your doctor tells you to do so.

PREXOLAN may be taken with or without food.

You should swallow the tablets whole with water.

The number of tablets you take depends on the strength of the medicine.

For PREXOLAN 2,5 and PREXOLAN 5 (tablets): You may start with an initial dose of 5 mg to 10 mg once a day.
This dose may be changed to a higher or lower dose by your doctor as needed.

If you take more PREXOLAN than you should:

If you have taken more PREXOLAN than you should, you may experience the following symptoms: rapid beating of the heart, agitation/aggressiveness, problems with speech, unusual movements (especially of the face or tongue) and reduced level of consciousness.

Other symptoms may be: confusion, seizures (fits), coma, a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness, slowing of the breathing rate, aspiration (the sucking in of fluid or a foreign body into the airway when drawing breath), high blood pressure or low blood pressure, abnormal rhythms of the heart.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take PREXOLAN:

If you miss a dose of PREXOLAN, take it as soon as possible.

Do not take a double dose to make up for forgotten individual doses. Just carry on with your next dose as normal.

Effect when treatment with PREXOLAN is stopped:

Do not stop taking your tablets just because you feel better. It is important that you carry on taking PREXOLAN tablets for as long as your doctor tells you.

If you suddenly stop taking PREXOLAN, symptoms such as sweating, unable to sleep, trembling, anxiety or nausea and vomiting might occur.

If you have any further questions on the use of PREXOLAN, ask your doctor or pharmacist.

POSSIBLE SIDE EFFECTS

PREXOLAN can have side effects.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

If any of the following happens, stop taking PREXOLAN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- If you get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an allergic reaction.
- If you have muscle weakness, tenderness or pain, feel unwell or have a high temperature. You may have a rare but serious illness that can be life-threatening called rhabdomyolysis.
- If you have a combination of fever, fast breathing, fast heart rate, sweating, muscle stiffness and drowsiness or sleepiness or confusion, difficulty in walking, shake or unusual muscle movements which you cannot control. In rare cases there may be rolling of the eyes. These could be signs of a serious condition known as neuroleptic malignant syndrome.
- If you get any pain in your chest or legs, or begin to have breathing difficulties. These could be signs of a blood clot.
- If you get a painful erection of the penis unrelated to sexual activity that will not go away.
- If you notice yellowing of your skin or eyes and your urine becomes darker in colour, high temperature, feel tired, lose your appetite, have stomach pain and feel sick. These could be signs of liver or pancreas problems.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- If you have fits (seizures).

- Diabetes or the worsening of diabetes occasionally associated with ketoacidosis (ketones in the blood and urine shown in tests) or falling into a coma.
- If you have abnormal heart beat including a faster or slower than usual heart rate.
- Difficulty in controlling urine (urinary incontinence).

Tell your doctor if you notice any of the following:

Frequent side effects:

- Weight gain or feeling more hungry
- Sleepiness
- Dizziness
- Headache
- Restlessness
- Loss of strength
- Agitation
- Abnormal manner of walking (gait)
- Falls
- Problems with speech
- Parkinsonism (a syndrome characterised by trembling, stiffness and balance disorder, postural instability)
- Hallucinations
- Water retention leading to swelling of the hands, ankles or feet
- Dry mouth
- Constipation
- Rash
- Lung infection (pneumonia)
- Increases in the levels of prolactin in the blood (found by blood test).

Less frequent side effects:

- Changes in the levels of some blood cells and circulating fats (found through blood tests)
- Anxiety
- Mood changes (feeling high or hostile)
- Nervousness
- Stuttering
- Fits
- Fast or slow heart rate or abnormal rhythms of the heart
- Sensitivity to sunlight
- Extreme tiredness.

Not all side effects reported for PREXOLAN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PREXOLAN, please consult your healthcare provider for advice.

STORING AND DISPOSING OF PREXOLAN

Store at or below 25 °C protected from light and moisture.

Keep the blisters in the carton until required for use.

Do not store in bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

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

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF PREXOLAN

28 or 30 film-coated tablets are packed in a polyamide, aluminium, polyvinyl chloride film and sealed with an aluminium foil backing. The blister strips (7 tablets/blister or 10 tablets/blister) are packed into an outer cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF PREXOLAN

PREXOLAN 2,5: White, round, biconvex, film-coated tablets with dimensions 6,1 mm ± 0,1 mm in diameter and 2,6 mm ± 0,2 mm in thickness.

PREXOLAN 5: White, round, biconvex, film-coated tablets with dimensions 8,1 mm ± 0,1 mm in diameter and 3,1 mm ± 0,2 mm in thickness.

PREXOLAN 10: White, round, biconvex, film-coated tablets with dimensions 10,1 mm ± 0,1 mm in diameter and 4,1 mm ± 0,2 mm in thickness.

REGISTRATION NUMBER

PREXOLAN 2,5: 43/2.6.5/0908

PREXOLAN 5: 43/2.6.5/0909

PREXOLAN 10: 43/2.6.5/0910

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912 (South Africa)

DATE OF PUBLICATION

Dates of registration:

PREXOLAN 2,5: 06 March 2014

PREXOLAN 5: 06 March 2014

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Date of the most recent amendment to the patient information leaflet as approved by the Authority: 06 March 2014

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