PATIENT INFORMATION LEAFLET

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)

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

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

WHAT PREXOLAN ODT CONTAINS

The active substance in PREXOLAN ODT 5 is 5 mg of olanzapine.

The other ingredients are colloidal silicon dioxide, crospovidone, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, mint powder, talc.

Contains sugar:

Lactose monohydrate 60,60 mg

The active substance in PREXOLAN ODT 10 is 10 mg of olanzapine.

The other ingredients are colloidal silicon dioxide, crospovidone, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, mint powder, talc.

Contains sugar:

Lactose monohydrate 121,20 mg

The active substance in PREXOLAN ODT 15 is 15 mg of olanzapine.

The other ingredients are colloidal silicon dioxide, crospovidone, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, mint powder, talc.

Contains sugar:

Lactose monohydrate 181,80 mg

The active substance in PREXOLAN ODT 20 is 20 mg of olanzapine.

The other ingredients are colloidal silicon dioxide, crospovidone, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, mint powder, talc.

Contains sugar:

Lactose monohydrate 242,40 mg

WHAT PREXOLAN ODT IS USED FOR

PREXOLAN ODT belongs to a group of medicines called antipsychotics.

- PREXOLAN ODT is used to treat a disease with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn. People with this disease may also feel depressed, anxious or tense.
- PREXOLAN ODT is also used to treat a condition with symptoms such as feeling “high”, having excessive amounts of energy, needing much less sleep than usual, talking very quickly with racing ideas and sometimes severe irritability. It is also a mood stabiliser that prevents further occurrences of the disabling high and low (depressed) extremes of mood associated with this condition.

BEFORE YOU TAKE PREXOLAN ODT

Do not take PREXOLAN ODT if you:

- Have a hypersensitivity or are allergic to PREXOLAN ODT or any of the other ingredients in PREXOLAN ODT. An allergic reaction may be recognised as a rash, itching, a swollen face, swollen lips or shortness of breath. If this has happened to you, tell your doctor.
- Are a child under the age of 18 years.
- Have been previously diagnosed with eye problems such as certain kinds of glaucoma (increased pressure in the eye).
- > 80 years of age.

Take special care with PREXOLAN ODT:

If you suffer from any of the following illnesses, you should contact your doctor as soon as possible:

- The use of PREXOLAN ODT in elderly patients with mental deterioration (dementia) is

not recommended as it may have serious side effects.

- Medicines of this type may cause a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness. If this happens, contact your doctor at once.
- Medicines of this type may cause unusual movements mainly of the face or tongue. If this happens after you have been given PREXOLAN ODT, tell your doctor.
- If you are having any blood tests, tell your doctor you are using PREXOLAN ODT, because it sometimes causes changes in a variety of blood tests/results or investigations and your doctor should be made aware of this.

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

- Seizures/fits or epilepsy
- High blood sugar levels or diabetes
- Increased levels of prolactin in the blood, found by blood test (hyperprolactinaemia)
- Problems with your liver (not functioning well)
- Heart disease
- Blood disorders
- If you are an elderly patient (> 65 years of age)
- Prostate problems
- 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, transient ischaemia attack (disturbances of body function lasting for less than 24 hours and caused by localised nervous system defects) in the elderly
- Difficulty in swallowing (risk of dysphagia)
- Suicide attempt while on PREXOLAN ODT therapy
- If you are a smoker because the combined effects of age, smoking and gender could lead to slower metabolism of PREXOLAN ODT.

Taking PREXOLAN ODT with food and drink:

Do not drink any alcohol if you have been given PREXOLAN ODT as PREXOLAN ODT and alcohol together may make you feel drowsy.

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

You may take PREXOLAN ODT with or without food.

Pregnancy and breastfeeding:

You should not take PREXOLAN ODT if you are pregnant or breastfeeding. If you are pregnant or breastfeeding your baby please consult your healthcare provider for advice before taking PREXOLAN ODT.

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

Driving and using machinery:

PREXOLAN ODT may cause you to feel sleepy.

Make sure you know how PREXOLAN ODT 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 ODT:

PREXOLAN ODT contains 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/fructose or galactose intolerance should not take PREXOLAN ODT. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking PREXOLAN ODT.

Taking other medicines with PREXOLAN ODT:

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

You might feel drowsy if PREXOLAN ODT is taken in combination with antidepressants or medicines taken for anxiety or to help you sleep (tranquillisers).

You should tell your doctor if you are taking:

- Fluoxetine (an antidepressant)
- Levodopa, normally given to patients suffering from Parkinson's disease
- Any antihypertensive medication (used for high blood pressure)
- Medication that may prolong the QTc interval. Caution is advised in patients with slow heart beat, 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)
- Activated charcoal
- Carbamazepine for epilepsy as it can lower the effect of PREXOLAN ODT
- Fluvoxamine (an antidepressant), or other antidepressants, ciprofloxacin (an antibiotic), ketoconazole (an antifungal) or antacids, as it may be necessary to decrease/change your PREXOLAN ODT dose.

The dose of your PREXOLAN ODT may also be adjusted if you are a smoker, ensure your doctor is aware if you smoke.

HOW TO TAKE PREXOLAN ODT

Do not share medicines prescribed for you with any other person. It may harm them, even if their symptoms are the same as yours.

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

Your doctor will decide how much PREXOLAN ODT you should take, usually PREXOLAN ODT tablets are taken once a day with or without meals.

You may start with an initial dose of 5 mg to 10 mg per day, with a target dose of 10 mg per day within several days. Depending on your response, your doctor will decide if the dose needs to be adjusted.

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

Place your PREXOLAN ODT orodispersible tablet in the mouth, where it will rapidly dissolve in the saliva so that you can easily swallow it. Alternatively, you may disperse it in a full glass of water and then immediately drink it. Do not remove the tablets from the blister foil until immediately before you need to take it.

If you take more PREXOLAN ODT than you should:

Patients who have taken more PREXOLAN ODT than they should have experienced 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, contact the nearest hospital or poison control centre.

If you forget to take PREXOLAN ODT:

If you miss a dose of PREXOLAN ODT, 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 ODT is stopped:

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

If you suddenly stop taking PREXOLAN ODT, 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 this product, ask your doctor or pharmacist.

POSSIBLE SIDE EFFECTS

PREXOLAN ODT can have side effects.

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

If any of the following happens, stop taking PREXOLAN ODT 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.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PREXOLAN ODT. You may need urgent medical attention or hospitalisation.

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

- 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.
- 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 passing urine (urinary hesitation).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been frequently reported:

- Weight gain or feeling more hungry
- Sleepiness
- Dizziness
- Headache
- Restlessness
- Parkinsonism (a syndrome characterised by trembling, stiffness and balance disorder, postural instability)
- Hallucinations
- Loss of strength
- Agitation
- Abnormal manner of walking (gait)
- Falls
- Problems with speech
- Poor or indistinct vision in an eye
- Water retention leading to swelling of the hands, ankles or feet
- Runny nose
- Dry mouth
- Constipation

- Rash
- Loss of bladder control (urinary incontinence)
- Lung infection (pneumonia)
- Increases in the levels of prolactin in the blood (found by blood test).

The following side effects have been reported less frequently:

- Changes in the levels of some blood cells and circulating fats (found through blood tests)
- Memory loss
- Anxiety
- Mood changes (feeling “high” or hostile)
- Nervousness
- Stuttering
- Sudden unexplained death
- Cough
- Sensitivity to sunlight
- Hair loss
- Extremity pain (other than joint)
- Menstrual changes.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF PREXOLAN ODT

Store at or below 30 °C.

Protect from light.

Keep the blisters in the carton until required for use.

Do not store in a 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 ODT

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.

IDENTIFICATION OF PREXOLAN ODT

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.

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

PHARMACARE LIMITED

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