APPROVED PATIENT INFORMATION LEAFLET FOR ZOLANZ 5 and 10 TABLETS

SCHEDULING STATUS

Schedule 5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ZOLANZ 5 TABLETS (film coated tablets)

ZOLANZ 10 TABLETS (film coated tablets)

Please read this leaflet carefully before taking ZOLANZ TABLETS.

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

Active ingredient:

Each tablet contains 5 mg or 10 mg olanzapine respectively.

The other ingredients are crospovidone, hypromellose, lactose monohydrate, magnesium stearate and Opadry White (containing lecithin, talcum, titanium oxide and xanthan gum).

Contains sugar: lactose monohydrate.

2. WHAT ZOLANZ TABLETS ARE USED FOR

ZOLANZ TABLETS are used in the treatment of psychotic disorders. It may also be used in certain cases of mania.

3. BEFORE YOU TAKE ZOLANZ TABLETS

Do not take ZOLANZ TABLETS:

- If you are allergic (hypersensitive) to olanzapine or any of the other ingredients in **ZOLANZ TABLETS** (see **WHAT ZOLANZ TABLETS CONTAINS**).
- If you have been previously diagnosed with or suffer from an eye disorder called narrow-angle glaucoma (a condition where pressure suddenly builds up inside your eye, which can cause permanent damage).
- If you or your child are under the age of 18 years.

Take special care with ZOLANZ TABLETS:

Inform your doctor immediately:

- If you want to stop taking **ZOLANZ TABLETS**. Reactions such as vomiting, diarrhoea and sleeping disorders may occur within a week after stopping **ZOLANZ TABLETS**, therefore your doctor will tell you how to do it gradually.
- If you experience abnormally high fever, sustained muscle spasm, abnormal behaviour, irregular heartbeat, changes in blood pressure or sweating, **ZOLANZ TABLETS** should be stopped. Please consult your doctor immediately.
- If you have a history of seizures (fits) or suffer from epilepsy.
- If you experience uncontrolled movements in your limbs, contact your doctor. Your doctor may change your dose or stop your treatment with **ZOLANZ TABLETS**.
- If you have a history or suffer from a liver disorder, if you have hepatitis, or if you are being treated with medicines which are potentially harmful to the liver.
- If you are an elderly person who suffers from dementia (a decline in mental reasoning, which include loss of communication, judgement and physical abilities).
- If you have a history or suffer from any heart problems.
- If you have a history or suffer from high blood pressure. Have your blood pressure checked regularly when using **ZOLANZ TABLETS** especially if you are older than 65 years of age.

- If you have a family history, are at risk of developing, or suffer from high blood sugar (diabetes).
- If you have breast cancer or have had breast cancer previously.
- If you have Parkinson's disease.
- If you have prostate problems (enlarged prostate gland) or problems with your intestines (paralysis of the intestines).
- If you have difficulty to swallow. **ZOLANZ TABLETS** can cause the inhalation of foreign material (such as food, saliva or stomach contents) into your lungs.
- If you experience a sudden drop in your blood pressure when you stand up (light-headedness, dizziness, faster heartbeat or fainting). If you have an infection, receive treatment for any type of cancer or if you have a bone marrow disorder.
- If you are taking any other medicine for psychotic disorders.
- If you suffer from a lung disease.
- If you have depression or suicidal feelings.
- **ZOLANZ TABLETS** may interfere with laboratory tests and results. Please inform you doctor or nurse that you are taking **ZOLANZ TABLETS**.
- **ZOLANZ TABLETS** may disrupt the ability of your body to reduce body temperature. Take special care when doing exercise or any activities that may increase your body temperature.

Taking ZOLANZ TABLETS with food and drink:

You may take **ZOLANZ TABLETS** with or without food. Do not take alcohol with **ZOLANZ TABLETS** as it may increase drowsiness.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional before taking **ZOLANZ TABLETS**.

Safety of **ZOLANZ TABLETS** during pregnancy and breastfeeding has not been established.

Do not take **ZOLANZ TABLETS** if you are pregnant, suspect that you are pregnant or breastfeeding.

Driving and using machinery:

ZOLANZ TABLETS may make you drowsy. Do not drive a vehicle or operate any machinery until you know how **ZOLANZ TABLETS** affects you.

Important information about some of the ingredients of ZOLANZ TABLETS:

ZOLANZ TABLETS contains lactose monohydrate, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (you have an intolerance to some sugars), talk to your doctor before taking **ZOLANZ TABLETS**.

Taking other medicines with ZOLANZ TABLETS:

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

The following medicines may cause an interaction when used in combination with **ZOLANZ TABLETS**:

- Certain central nervous system depressants (such as tranquillisers, including alcohol).
- Levodopa or dopamine agonists (used to treat Parkinson's disease).
- Valproate or carbamazepine (used to treat epilepsy).
- Lithium (used to treat bipolar disorders and depression).
- Antihypertensive medication (used to treat high blood pressure).
- Medicine that prolong the QT interval (causes changes in the way your heart beats, which is visible on an electrocardiogram (ECG) machine).
- Fluoxetine or fluvoxamine (used to treat depression).
- Omeprazole (used to treat stomach ulcers).
- Rifampicin (used to treat tuberculosis (TB)).
- Ciprofloxacin (used to treat bacterial infections).

- Ketoconazole (used to treat fungal infections).
- Activated charcoal (used to treat poisonings). Take it at least 2 hours before or after taking **ZOLANZ TABLETS**.
- Smoking.

4. HOW TO TAKE ZOLANZ TABLETS

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

Always take **ZOLANZ TABLETS** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The dose of **ZOLANZ TABLETS** will be different for each patient and may depend on what it is being used for, your age and if other medicines are also being given or taken at the same time.

Your doctor will decide the appropriate dose for your condition and may adjust your dose according to your personal needs.

The usual dose is 10 mg daily.

The maximum dose is 20 mg daily.

Your doctor will tell you how long your treatment with **ZOLANZ TABLETS** will last. If you have the impression that the effect of **ZOLANZ TABLETS** is too strong or too weak, tell your doctor or pharmacist.

If you take more ZOLANZ TABLETS than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the rest of the remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take ZOLANZ TABLETS:

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take **ZOLANZ TABLETS** at the next regularly scheduled time.

Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

ZOLANZ TABLETS can have side effects. Not all side effects reported for **ZOLANZ TABLETS** are included in this leaflet.

Should your general health worsen or you experience any untoward effects while taking ZOLANZ TABLETS, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- Swelling of your hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **ZOLANZ TABLETS**. 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:

- Yellowing of your skin and eyes, also called jaundice or hepatitis.
- Chest pain.
- Changes in the way your heart beats (beating faster or slower than normal or skipping beats).
- Signs of recurrent infections, such as fever or sore throat.
- Unexplained bruising, pin point bleeds on your skin, nosebleeds or bleeding gums.
- Blockage of a vein in your body, including your legs or lungs (legs: pain, tenderness and swelling in the area of the blockage; lungs: chest pain, coughing and shortness of breath).

- Pneumonia (lung infection causing difficulty in breathing, coughing associated with fluids or phlegm and fever).
- Shortness of breath.
- Trouble in controlling urine (involuntary leakage of urine).
- Excessively high or low blood sugar that can make you lose consciousness (increased thirst, urination, tiredness, nausea, vomiting, hunger, irritability, irregular heartbeat, difficulty speaking or confusion).
- Excessively high levels of sugar in your blood that causes high levels of acidity in your body (nausea, vomiting, thirst, excessive urination, pain in the stomach area, and changes in the way your heart beats and in your blood pressure).
- Water poisoning. Excessive amounts of water that causes an electrolyte imbalance in your body (nausea, vomiting, headache, a fruity smell of your breath, confusion, loss of appetite, irritability, muscle weakness and tiredness).
- Seizures (fits).
- Neuroleptic malignant syndrome (NMS) (fever, tight/stiff muscles, altered mental status (feeling confused, agitated or disoriented), changes in the way your heart beats, changes in your pulse rate or blood pressure and increased sweating).
- Tardive dyskinesia (uncontrolled and repetitive movements of your lips, tongue, face, arms or legs, or excessive blinking of your eyes).

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

Tell your doctor as soon as possible if you notice any of the following:

Side effects that may occur more frequently include:

- Swelling of your feet or ankles due to water retention.
- Personality disorder (changes in your behaviour, difficulty adapting in society or with personal relationships).
- Mood or mental changes.
- Loss of memory (amnesia).

- Feeling anxious, nervous or agitated.
- Intense feelings of well-being, happiness, excitement and joy (euphoria).
- Hostile behaviour (unfriendliness, anger, hateful or spiteful behaviour).
- Restlessness.
- Dizziness.
- Parkinsonism (tremor, slow movements, rigidness and unstable posture).
- Twitching (uncontrolled movements).
- Low blood pressure when you get up too quickly (light-headedness or dizziness).
- High blood pressure.
- Constipation, dry mouth or increased appetite.
- Vaginal inflammation (itching, pain or discharge).
- Abnormally high levels of prolactin in your blood (in females it can cause little or no menstrual cycle, production of breast milk, tender breasts or loss of libido, while in men it can lead to erectile dysfunction, loss of libido and the formation of breast tissues).
- Weight gain.
- Flu-like symptoms (headache, aching muscles, tiredness).

Side effects that may occur less frequently include:

- Unusual drowsiness.
- Lack of feeling or emotion.
- Confusion.
- Difficulty sleeping.
- Headache.
- Difficulty speaking or stuttering.
- Numbing, tingling or burning feeling of your skin (“pins and needles”).
- Changes in walking and balance.
- Tremor (uncontrolled rhythmic muscle movements or twitches).
- Tightness of muscles.

- Problems with your eyesight.
- Sore throat or coughing.
- Indigestion (heartburn), stomach discomfort, nausea (feeling sick) or vomiting (being sick).
- Acne (pimples).
- Dry skin.
- Hair loss (temporary).
- Increased sensitivity of your skin to sunlight.
- Painful menstrual cycles (periods) if you are female.
- Weakness.
- Weight loss.
- Pain in your legs, feet, arms or hands.

Other side effects that may occur but the frequency is unknown, include the following:

- High cholesterol or fat levels in your blood.
- High blood sugar (increased thirst and urination).
- Double vision.
- Runny nose.
- Pancreatitis (pain in your stomach area radiating to your back).
- Increased saliva and thirst.
- Sweating.
- Breakdown of muscle tissue (muscle pain, tenderness or swelling, nausea, vomiting and confusion).
- Joint pain.
- Persistent, painful erection if you are male.
- Changes in your menstrual cycle (period) or spontaneous production of milk from your breasts if you are female.
- Decreased sexual drive.

- Symptoms of withdrawal once you stop taking **ZOLANZ TABLETS** (dizziness, tiredness, headache, tremor, sweating, nightmare, difficulty sleeping, nausea, vomiting or diarrhoea).

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

6. STORING AND DISPOSING OF ZOLANZ TABLETS

- Store at or below 25 °C in blister strips.
- Protect from light and moisture.
- Do not remove blister strips from outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF ZOLANZ TABLETS

ZOLANZ TABLETS are packed into aluminium/aluminium foil blister strips of 10 tablets each. Pack sizes of 10 (1 blister strips per cardboard box) or 30 (3 blister strips per unit carton).

8. IDENTIFICATION OF ZOLANZ TABLETS

ZOLANZ 5 TABLETS: White to off-white, round shaped, biconvex, film coated tablet, debossed with “ZP29” on one side and plain on the other side.

ZOLANZ 10 TABLETS: White to off-white, round shaped, biconvex, film coated tablet, debossed with “ZP31” on one side and plain on the other side.

9. REGISTRATION NUMBERS

ZOLANZ 5 TABLETS: 43/2.6.5/0666

ZOLANZ 10 TABLETS: 43/2.6.5/0667.

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Zydus Healthcare S.A. (Pty) Ltd

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11. DATE OF PUBLICATION

11 June 2015.