SCHEDULING STATUS

Schedule 5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ZIPOLA 2,5 film coated tablet

ZIPOLA 5 film coated tablet

ZIPOLA 10 film coated tablet

Read all of this leaflet carefully before you start taking ZIPOLA:

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

The active substance is 2,5 mg, 5 mg, or 10 mg olanzapine respectively.

The other ingredients are crospovidone, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose and Opadry White (containing lactose monohydrate, polyvinyl alcohol, talc, titanium dioxide and triacetin).

Contains sugar (lactose monohydrate).

2. WHAT ZIPOLA IS USED FOR

ZIPOLA belongs to a group of medicines called antipsychotics and is used to treat the following conditions:

- Schizophrenia: a condition where you feel you are not in contact with reality, with symptoms such as hearing, seeing or sensing things which are not there, disordered thinking, hostility, unusual suspiciousness, becoming withdrawn, showing a lack of emotion and lessening of speech fluency.
- Bipolar disorder: a manic-depressive mood disorder where you experience episodes of

elevated or agitated mood alternating with episodes of depression.

3. BEFORE YOU TAKE ZIPOLA

Do not take ZIPOLA if:

- You are hypersensitive (allergic) to olanzapine or any of the other ingredients of **ZIPOLA** (see **WHAT ZIPOLA CONTAINS**).
- You suffer from an eye disorder called narrow-angle glaucoma (causing increased pressure in your eye) or you are at risk of developing this condition.
- You or your child are under the age of 18 years. Safety and efficacy have not been established in patients younger than 18 years of age.

Take special care with ZIPOLA:

- If you want to stop taking **ZIPOLA** abruptly, reactions such as vomiting, diarrhoea and sleeping disorders may occur within a week after stopping **ZIPOLA**. Do not stop taking **ZIPOLA** unless your doctor tells you to.
- If you experience an abnormally high fever, continuous muscle spasm, abnormal behaviour, an irregular heartbeat, changes in your blood pressure or sweating, stop taking **ZIPOLA** and consult your doctor immediately.
- If you suffer from seizures (fits) or you have had a seizure previously.
- If you experience any uncontrolled movements in your limbs, contact your doctor. Your doctor may change your dose or stop your medicine.
- If you suffer from any liver condition, if you are taking medicine that affects your liver or you have hepatitis.
- If you are elderly and you suffer from a decline in mental reasoning, which includes loss of communication, judgement and physical abilities.
- If you have a family history of or suffer from high blood sugar (diabetes).
- If you have breast cancer or you have had breast cancer previously.
- If you have Parkinson’s disease.
- If you suffer from an enlarged prostate gland.

- If have a condition that causes blockage of your intestines, known as paralytic ileus.
- If you had a heart attack previously or you suffer from heart disease.
- If you had a stroke or are at risk of developing a stroke, or if you or someone in your family have a history of blood clots forming in your body.
- If you are elderly (older than 65 years of age).
- If you do strenuous exercise or you are exposed to conditions of extreme heat. **ZIPOLA** may disrupt the body's ability to reduce body temperature.
- If you have ever experienced difficulty swallowing.
- If you experience suicidal thoughts or tendencies, please consult your doctor or healthcare professional immediately.
- If you have a history of drug abuse.
- Weight gain has been seen in patients taking **ZIPOLA**. You and your doctor should check your weight regularly and consult with a dietician if necessary.
- High blood sugar and high levels of fat (triglycerides and cholesterol) have been seen in patients taking **ZIPOLA**. Your doctor will do blood tests to check your blood sugar and fat levels before you start taking **ZIPOLA** and regularly during your treatment.

ZIPOLA may interfere with laboratory tests and results. Please inform you doctor or nurse that you are taking **ZIPOLA**.

Taking ZIPOLA with food or drink:

ZIPOLA can be taken with or without food.

Do not drink alcohol if you are taking **ZIPOLA**, as it may make you feel drowsy.

Pregnancy and breastfeeding:

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

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

Driving and using machinery:

ZIPOLA may cause side effects, such as somnolence and dizziness. Do not drive a vehicle, operate machinery, or do anything else that require your attention until you know how **ZIPOLA** affects you.

Important information about some of the ingredients of ZIPOLA:

ZIPOLA contains lactose monohydrate 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 **ZIPOLA**.

Using other medicines with ZIPOLA:

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 **ZIPOLA**:

- Aluminium or magnesium antacids (used to treat heart burn, reflux or indigestion).
- Alcohol and smoking.
- Central nervous system (CNS) depressants (tranquillisers).
- Levodopa or dopamine agonists (used to treat Parkinson's disease).
- Carbamazepine or valproate (used to treat epilepsy/seizures).
- Anticholinergic medicine (used as muscle relaxants, to treat stomach cramps).
- Antihypertensive medicine (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).
- Omeprazole or cimetidine (used to treat stomach ulcers or acid reflux).
- Rifampicin (used to treat tuberculosis (TB)).
- Activated charcoal (used to treat poisonings).
- Fluvoxamine (used to treat depression).
- Ciprofloxacin (used to treat bacterial infections).
- Ketoconazole (used to treat fungal infections).

4. HOW TO TAKE ZIPOLA

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

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

Adults:

ZIPOLA should be taken once a day according to the doctor's instructions, with or without food, at the same time each day. The usual starting dose is one 5 mg or 10 mg tablet daily with a target dose of 10 mg per day within several days.

The maximum dose is 20 mg daily. Your doctor will decide the appropriate dose for you based upon your age and condition.

Your doctor will tell you how long your treatment with **ZIPOLA** will last. Do not stop treatment early without consulting your doctor or pharmacist.

If you have the impression that the effect of **ZIPOLA** is too strong or too weak, tell your doctor or pharmacist.

It is important to continue taking **ZIPOLA** for as long as your doctor tells you to, in order to maintain control of your condition, even if your symptoms come back. If your symptoms do come back, see your doctor but do not stop taking **ZIPOLA** until your doctor says so.

If you take more ZIPOLA than you should:

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

If you forget to take ZIPOLA:

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 **ZIPOLA** at the next regularly scheduled time.

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

Effects when treatment with ZIPOLA is stopped:

Do not suddenly stop taking **ZIPOLA** just because you feel better. It is important that you take **ZIPOLA** exactly as your doctor tells you.

If you suddenly stop taking **ZIPOLA**, symptoms such as sweating, inability to sleep, tremor, anxiety or nausea and vomiting might occur. Your doctor may suggest that you reduce the dose gradually before stopping treatment.

5. POSSIBLE SIDE EFFECTS

ZIPOLA can have side effects.

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

If any of the following happens, stop taking **ZIPOLA** 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, hives or itching.
- Fainting.

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

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

Frequent:

- Parkinsonism (tremor, slow movements, rigidness and unstable posture).
- Changes in the way your heart beats (beating faster or slower than normal or skipping beats).

- Pneumonia (lung infection causing difficulty in breathing, coughing associated with fluids or phlegm and fever).
- Excessively high levels of sugar in your blood that causes high levels of acidity in your body (nausea, vomiting, thirst, excessive urination, pain of the stomach area and changes in the way your heart beats and your blood pressure).

Less frequent:

- 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).
- Excessive amounts of water that causes an electrolyte imbalance in your body (nausea, vomiting, headache, 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).
- Chest pain.
- Abnormal readings on an electrocardiogram (ECG) when tests are done.
- Breakdown of muscle tissue (muscle pain, tenderness or swelling, nausea, vomiting and confusion).
- High blood pressure.
- Pancreatitis (pain in your stomach radiating to your back).
- Inflammation of your liver, causing yellowing of the skin and whites of your eyes, also called jaundice.
- Blockage of a vein in your body (pain, tenderness and swelling in the area of the blockage).
- Hypothermia (severe drop in body temperature causing shivering, confusion, drowsiness).

  Frequency unknown:

- An allergic reaction with flu-like symptoms (a rash on your face, high temperature, enlarged lymph nodes, increased levels of liver enzymes and white blood cells when blood tests are done).

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:

Frequent:

- Changes in the number of white blood cells in your blood when blood tests are done.
- 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).
- High cholesterol or fat levels in your blood.
- Increase in levels of uric acid and enzymes levels in your blood.
- Weight gain.
- Drowsiness.
- Dizziness.
- Changes in the way you walk or falling easily.
- Difficulty speaking, trouble articulating words or stuttering.
- Tremor (uncontrolled twitching or shaking).
- Restlessness, abnormal or impaired voluntary movement.
- Lazy eye (poor vision in one eye).
- Light-headedness or dizziness when you stand up to quickly.
- Constipation or indigestion.
- Dry mouth.
- Involuntary leakage of urine.
- Runny nose.
- Acne (pimples).
- Dry skin or sweating.
- Reddening of your skin.

- Swelling of your face, legs, feet, arms or body due to water retention.
- Abnormal weakness or tiredness.
- Increased appetite.
- Decreased sexual drive (libido).
- Erection problems in men.
- Hallucinations (seeing, hearing or sensing things that are not real).

Less frequent:

- Unexplained bruising, pin point bleeds on your skin, nosebleeds or bleeding gums.
- Weight loss.
- Feeling agitated, anxious, nervous or confused.
- Personality disorder (changes in your behaviour, difficulty adapting in society or with personal relationships).
- Mood swings.
- Loss of memory.
- Intense feelings of well-being, happiness, excitement and joy (euphoria).
- Hostile behaviour (unfriendliness, anger, hateful or spiteful behaviour).
- Difficulty sleeping.
- Headache.
- Difficult, uncontrolled movements.
- Twitching.
- Numbing, tingling or burning feeling of your skin.
- Tardive dyskinesia (uncontrolled and repetitive movements of your lips, tongue, face, arms or legs, or excessive blinking of your eyes).
- Problems with your eyesight or double vision.
- Low blood pressure (light-headedness or dizziness).
- Shortness of breath or coughing.
- Throat infection.
- Nausea (feeling sick), vomiting (being sick), increased saliva and thirst.

- Pain of your stomach area, bulging of your stomach.
- Severe sensitivity of your skin to sunlight.
- Joint pain.
- Vaginal inflammation (discharge or itching).
- Changes in your menstrual cycle (period) or painful menstrual cycles.
- Persistent, painful erection.
- Breast changes in men and women (such as abnormal production of breastmilk or abnormal growth), an abnormal absence of menstruation.
- Flu-like symptoms (headache, aching muscles, tiredness).
- Pain in your legs, feet, arms or hands.
- Problems in starting the urine stream when wanting to urinate, inability to completely empty the bladder.

Frequency unknown:

- Hair loss (temporary).

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

6. STORING AND DISPOSING OF ZIPOLA

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

7. PRESENTATION OF ZIPOLA

ZIPOLA is packed 1 x 10 tablets in silver Alu/Alu blister strips.

ZIPOLA 2,5 & 5: 3 or 13 blister strips of 10 tablets (30 or 130 tablets) are placed inside a cardboard box.

ZIPOLA 10: 3 or 10 blister strips of 10 tablets (30 or 100 tablets) are placed inside a cardboard box.

8. IDENTIFICATION OF ZIPOLA

ZIPOLA 2,5: Off-white to pale yellow, round, biconvex, film coated tablets, debossed with “J” on one side and “2,5” on the other side.

ZIPOLA 5: Off-white to pale yellow, round, biconvex, film coated tablets, debossed with “J” on one side and “5” on the other side.

ZIPOLA 10: Off-white to pale yellow, round, biconvex, film coated tablets, debossed with “J” on one side and “10” on the other side.

9. REGISTRATION NUMBERS

ZIPOLA 2,5: 46/2.6.5/0667

ZIPOLA 5: 46/2.6.5/0668

ZIPOLA 10: 46/2.6.5/0669

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Jubilant Pharma SA (Pty) Ltd

24 Parrot Avenue,

Extension 1, Lenasia,

Johannesburg,

1820

11. DATE OF PUBLICATION

29 September 2017