PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S5**

ZYPREXA IM (powder for solution for injection)

Olanzapine

Contains sugar: 50 mg lactose monohydrate

Read all of this leaflet carefully before you are given ZYPREXA IM.

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

1. What ZYPREXA IM is and what it is used for

ZYPREXA IM contains the active substance olanzapine. ZYPREXA IM belongs to a group of medicines called antipsychotics.

ZYPREXA IM is used to treat the following conditions:

- **Schizophrenia,** 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mistaken beliefs, unusual suspiciousness, and becoming withdrawn.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 and tense.

- **Acute mania,** a condition with symptoms of excitement or euphoria, in patients with Bipolar I disorder.

ZYPREXA IM injection is given when rapid control of agitation and distressing behaviour is needed and treatment with ZYPREXA tablets is not appropriate. Your doctor will change your treatment to ZYPREXA tablets, as soon as appropriate.

2. What you need to know before you are given ZYPREXA IM

You should not be given ZYPREXA IM:

- If you are allergic (hypersensitive) to olanzapine or any of the ingredients of ZYPREXA IM injection (listed in section 6). 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.
- If you have been previously diagnosed with eye problems such as certain kinds of glaucoma (increased pressure of the eye).

Safety and efficacy of ZYPREXA IM injection in children below 18 years of age have not been established.

Warnings and precautions

Talk to your doctor or nurse before you are given ZYPREXA IM injection.

- Tell the doctor or nurse if you feel dizzy or faint after the injection. You will probably need to lie down until you feel better. The doctor or nurse may also want to measure your blood pressure and pulse.
- The use of ZYPREXA IM injection in elderly patients with dementia is not recommended as it may have serious side effects.
- ZYPREXA IM injection may cause a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness. If this happens, contact your doctor at once.

- ZYPREXA IM injection may cause unusual movements mainly of the face or tongue. If this happens after you have been given ZYPREXA IM injection, tell your doctor.
- ZYPREXA IM injection may cause allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature, enlarged lymph nodes, increased levels of liver enzymes seen on blood tests and an increase in a type of white blood cells (eosinophilia). If this happens, tell your doctor.
- ZYPREXA IM injection may cause high blood sugar and high level of fat (triglycerides and cholesterol) have been seen in patients taking this medicine. Your doctor should do blood tests to check blood sugar and certain fat levels before you start taking ZYPREXA IM injection and regularly during treatment.
- ZYPREXA IM injection may cause elevations of liver enzymes, tell your doctor if this happens, if you suffer from a liver disease or if you are treated with medicines that can potentially damage the liver.
- ZYPREXA IM injection may cause dysphagia. Tell your doctor if you are at risk for aspiration pneumonia (lung infection due to the inhalation of stomach content and/or secretion of oropharynx).
- Tell the doctor if you or someone else in your family has a history of blood clots, as ZYPREXA IM has been associated with formation of blood clots.

- If you suffer from any of the following illnesses tell your doctor as soon as possible:
  - stroke or “mini” stroke (temporary symptoms of stroke)
  - Parkinson’s disease
  - prostate problems
  - a blocked intestine (paralytic ileus)
  - increased pressure in the eye (glaucoma)
  - liver or kidney disease
  - blood disorders
  - heart disease
  - diabetes
  - seizures

- If you suffer from dementia, you or your carer/relative should tell your doctor if you have ever had a stroke or “mini” stroke.
- As a routine precaution, if you are over 65 years your blood pressure may be monitored by your doctor.

Other medicines and ZYPREXA IM

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines). Especially tell your doctor if you are taking medicines for Parkinson’s disease.

A combination of ZYPREXA IM injection with the following medicines might make you feel drowsy: medicines taken for anxiety or to help you sleep (tranquilisers, including benzodiazepines) and antidepressants. Only take other medicines while you are on ZYPREXA IM injection if your doctor tells you that you can.

If you receive ZYPREXA IM injection, a benzodiazepine injection is not recommended at the same time as this may result in excessive sleepiness, may have serious effects on your heart rate or your breathing, and, in very rare cases, may result in death. If your doctor has to give a benzodiazepine injection to treat your condition, there should be at least a one hour time period after the ZYPREXA IM injection and you are to be monitored closely after the benzodiazepine injection is given.

Receiving ZYPREXA IM with food and drink:

Do not drink any alcohol if you have been given ZYPREXA IM injection as together with alcohol it may make you feel drowsy.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

- **Usage in pregnancy:**

The safety of ZYPREXA IM injection in pregnancy has not been established.

The following symptoms may occur in newborn babies, of mothers that have used ZYPREXA in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or_weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

- **Usage during breastfeeding:**

The safety of ZYPREXA IM injection has not been established in breastfeeding women.

Driving and using machinery:

ZYPREXA IM injection may make you feel drowsy. If this happens do no drive or operate any tools or machines. Tell your doctor.

It is not always possible to predict to what extent ZYPREXA IM may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ZYPREXA IM affects you.

ZYPREXA IM contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How ZYPREXA IM is given

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

You will not be expected to give yourself ZYPREXA IM injection. It will be given to you by a person who is qualified to do so.

Your doctor will decide how much ZYPREXA IM injection you need and how long you need it for. The dose is usually 10 mg for the first injection, but it may be less than this. Up to 30 mg in 24 hours may be given. The dose for patients aged over 65 years is 2,5 mg or 5 mg.

ZYPREXA IM injection comes as a powder. Your doctor or nurse will make it up into a solution. ZYPREXA IM injection is for intramuscular use. The correct amount of solution will be injected into your muscle.

If you are given more ZYPREXA IM injection than you should be:

Since a healthcare provider will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

- Symptoms of overdose include: 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: acute confusion, seizures (epilepsy), coma, a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness, slowing of the breathing rate, aspiration, high blood pressure or low blood pressure, abnormal rhythms of the heart.

Tell your doctor or nurse of your concern.

Only a few doses of ZYPREXA IM injection are needed. Your doctor will decide when you need a dose of ZYPREXA IM injection.

If you have further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

ZYPREXA IM injection can have side effects.

Not all side effects reported for ZYPREXA IM injection are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while being given ZYPREXA IM injection, please tell your doctor or nurse for advice.

Tell your doctor immediately if you have:

- unusual movement (a frequent side effect) mainly of the face or tongue;
- blood clots in the veins (less frequent side effect) especially in the legs (symptoms include swelling, pain, and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately;

- a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness (frequency cannot be estimated).

Frequent side effects for ZYPREXA IM:

slower or faster heart rate;

low blood pressure;

some people may feel dizzy or faint (with a slow heart rate) after injection, especially when getting up from lying or sitting position. This will usually pass on its own but if it does not, tell your doctor or nurse as soon as possible.

Less frequent side effects for ZYPREXA IM:

- breathing more slowly
- abnormal heart rhythms

In addition, the following side effects have been seen after patients have taken ZYPREXA orally:

Frequent side effects:

- loss of strength;
- weight gain;
- extreme tiredness;
- some people may feel dizzy or faint (with a slow heart rate), especially when getting up from lying or sitting position. This will usually pass on its own but if it does not, tell your doctor;
- constipation;
- dry mouth;
- feeling more hungry;
- increases or decreases of level of certain types of white blood cells;
- water retention leading to swelling of the hands, ankles or feet;
- joint pain;
- restlessness;

- dizziness;
- sleepiness;
- increases in liver enzymes;
- increases in the levels of circulating fats;
- increases in the levels of sugars in the blood and urine;
- increases of level of prolactin in the blood;
- increases in levels of uric acid in the blood;
- sexual dysfunctions such as decreased libido in males and females or erectile dysfunction in males.

Less frequent side effects:

- hypersensitivity (e.g. swelling in the mouth and throat, itching, rash);
- sensitivity to sunlight;
- slow heart rate;
- inflammation of the pancreas causing severe stomach pain, fever and sickness;
- decreases of level of blood platelets;
- liver inflammation;
- liver disease appearing as yellowing of the skin and white parts of the eyes;
- diabetes and worsening of diabetes occasionally associated with ketoacidosis (ketones in the blood and urine) or coma;
- muscle disease presenting as unexplained aches and pains;
- restless leg syndrome;
- seizures, usually associated with a history of seizures (epilepsy);
- problems with speech (stuttering);
- prolonged and/or painful erection;
- bleeding from nose;
- hair loss;
- rash;
- increases in the levels of creatine phosphokinase in the blood;

- allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature, enlarged lymph nodes, increased levels of liver enzymes seen on blood tests and an increase in a type of white blood cells (eosinophilia).

While receiving ZYPREXA IM, elderly patients with dementia of the Alzheimer's type may suffer from stroke, pneumonia, urinary incontinence, lack of ability to urinate, falls, extreme tiredness, visual hallucinations, a rise in body temperature, redness of the skin and have trouble walking. Some fatal cases have been reported in this particular group of patients.

In patients with Parkinson's disease ZYPREXA IM may worsen the symptoms.

Patients with bipolar mania receiving ZYPREXA IM in combination with lithium or valproate may get the following side effects: weight gain, fever, abdominal distension, dry mouth, feel more hungry, memory loss or forgetfulness, problems with speech, tremor.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ZYPREXA.

5. How to store ZYPREXA IM

Store all medicines out of reach of children.

Store at or below 25 °C. Do not freeze. Protect from light and moisture.

After ZYPREXA IM Injection is made into a solution, use within one hour. The reconstituted medicine is

stable for one hour when stored at or below 25 °C. Do not freeze after reconstitution.

Discard any unused contents.

6. Contents of the pack and other information

What ZYPREXA IM contains

Each vial of ZYPREXA IM contains 10 mg of the active substance olanzapine.

The other ingredients are lactose monohydrate, tartaric acid, water for injection, tartaric acid, hydrochloric acid solution, sodium hydroxide solution.

What ZYPREXA IM looks like and contents of the pack

ZYPREXA IM (powder for solution for injection) is a yellow, sterile, lyophilised plug.

ZYPREXA IM is packed in a 5 ml size Type I flint glass vial closed with a rubber stopper and sealed with an aluminium cap.

ZYPREXA IM vials are supplied as singles.

Holder of Certificate of Registration

7. HOLDER OF CERTIFICATE OF REGISTRATION

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