Date of submission: 04/03/2022
*Post registration amendment (0006)*

# AMENDED PROPOSED PATIENT INFORMATION LEAFLET (CLEAN COPY)

**SCHEDULING STATUS**

S5

**ALONZA 2,5 / 5 / 10 mg** (film-coated tablet)

Olanzapine

Contains sugar (lactose)

**Read all of this leaflet carefully before you are given ALONZA**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other health care provider.
- **ALONZA** 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 **ALONZA** is and what it is used for
2. What you need to know before you use **ALONZA**
3. How to use **ALONZA**
4. Possible side effects
5. How to store **ALONZA**
6. Contents of the pack and other information

## 1. What ALONZA is and what it is used for

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

- Psychotic disorders like 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hearing, seeing or sensing things which are not there, disordered thinking, hostility, unusual suspiciousness, becoming withdrawn, showing a lack of emotion and lessening of speech fluency.

- Acute episodes of mania, a condition with symptoms of excitement or euphoria and in the prevention of acute episodes of bipolar disorder: a manic-depressive mood disorder where you experience episodes of elevated or agitated mood alternating with episodes of depression.

**2. What you need to know before you use ALONZA**

**Do not take ALONZA:**

- If you are hypersensitive (allergic) to any of the components of **ALONZA (see "WHAT ALONZA CONTAINS").**
- If you have an eye condition known as narrow-angle glaucoma where pressure suddenly builds up inside of your eye which can cause permanent damage.
- If you or your child is under the age of 18 years. Safety and efficacy have not been established in patients younger than 18 years of age.

**Warnings and precautions:**

If you stop taking **ALONZA**. You should gradually be weaned of your medication. You should not suddenly stop taking **ALONZA**, as it can cause a reaction with symptoms such as sweating and salivating profusely, nausea, vomiting, diarrhoea, feeling anxious or agitated, having difficulty sleeping and tremor (uncontrolled twitch/shaking).

If you develop any signs or symptoms of neuroleptic malignant syndrome (NMS) such as a fever, tight/stiff muscles, altered mental status (feeling confused, agitated or disoriented), changes in the way your he art beats, changes in your pulse rate or blood pressure and increased sweating, contact your doctor immediately.

If you develop any signs or symptoms of tardive dyskinesia (a condition where you develop uncontrolled and repetitive movements of your lips, tongue, face, arms or legs or excessive blinking of your eyes), contact your doctor immediately.

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Tell you healthcare provider:

- If you suffer from seizures (fits) or you have had a seizure previously.
- If you suffer from any liver condition, you are taking medication that affects your liver or you have hepatitis.
- If you have diabetes (high blood sugar) or you are at risk of developing diabetes (you are obese or you have a family member who have diabetes). Contact your doctor if you develop symptoms, such as an increased thirst or hunger, frequent urination or a feeling of unusual weakness, while you are taking **ALONZA**.
- If you suffer from dementia or Alzheimer's disease (forgetfulness, confusion, changes in your mood, difficulty communicating).
- If you suffer from any condition or disease (such as bone marrow depression), or you are taking any medication (such as radiation- or chemotherapy) which affects your blood cells.
- If you have difficulty swallowing. **ALONZA** can cause the inhalation of foreign material (food, saliva or stomach contents) into your lungs.
- If you have had any suicidal notions.
- If you suffer from any heart problems (heart attack, heart disease or heart failure), or you have had a stroke or are at risk of developing a stroke.
- If you are dehydrated or have lost a lot of fluids or blood.
- If you do strenuous exercise or you are exposed to conditions of extreme heat.
- If you suffer from an enlarged prostate gland.
- If have a condition that causes blockage of your intestines, known as paralytic ileus.
- If you are elderly (older than 65 years of age).
- If you are elderly and have experienced loss of memory and hallucinations or you have a history of heart problems, stroke or you are a smoker.
- If you have breast cancer or you have had breast cancer previously.
- If you have Parkinson's disease.
- If you are not mobile or you have a history of blood clot formation.

- If you have abnormally high cholesterol levels

**Other medicines and ALONZA**

Always tell your health care provider if you are taking any other medicines. (This includes all complementary or traditional medicines).

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

- Alcohol and smoking.
- Carbamazepine or valproate (used to treat epilepsy/seizures).
- Omeprazole (used to treat stomach ulcers or acid reflux).
- Rifampin (used to treat tuberculosis (TB)).
- Fluvoxamine, fluoxetine or tricyclic antidepressants such as imipramine, desipramine, theophylline or diazepam (used to treat depression).
- Ciprofloxacin (used to treat bacterial infections).
- Activated charcoal (used to treat poisonings).
- Aluminium or magnesium antacids (used to treat heart burn, reflux or indigestion).
- Levodopa (used to treat Parkinson's disease).
- Lithium (used to treat bipolar disorders and depression).
- Central nervous system (CNS) depressants (tranquillisers).
- Medicine that prolong the QT interval (causes changes in the way your heart beats which is visible on an electrocardiogram (ECG) machine).
- Antihypertensive medication (used to treat high blood pressure).
- Anticholinergic medication (used as muscle relaxants, to treat stomach cramps).
- Medication that severely affects your liver.

**ALONZA with food, drink and alcohol**

Do not drink any alcohol if you have been taking **ALONZA** as together with alcohol it may make you feel

drowsy.

**ALONZA** can be taken with or without food.

**Pregnancy, breastfeeding and fertility**

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

Do not take **ALONZA** if you are pregnant or breastfeeding your baby.

The following symptoms may occur in newborn babies, born to mothers who have taken **ALONZA**: agitation, tremors, sleeplessness, breathing problems or difficulty feeding. If you notice any of these symptoms, contact your doctor.

**Driving and using machines**

**ALONZA** may impair your ability to drive and use machinery. Do not drive a vehicle, operate machinery, or do anything else that require your attention until you know how **ALONZA** affects you.

**Important information about some of the ingredients of ALONZA:**

**ALONZA** contains lactose 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 **ALONZA**.

## 3. How to use ALONZA

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

Always take **ALONZA** exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **ALONZA** is too strong or too weak, talk to your doctor or pharmacist.

The usual dose is 10 mg daily. Your doctor may adjust your dose according to your personal needs.

The maximum dose is 20 mg daily.

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Your doctor will tell you how long your treatment with **ALONZA** will last.

**Taking ALONZA with food or drink:**

**ALONZA** can be taken with or without food.

**If you take more ALONZA than you should:**

In the event of an overdose, contact 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.

You may experience the following symptoms is you have taken too much **ALONZA:** rapid beating of the heart, feeling agitated or aggressive, difficulty speaking, muscle spasms, tremors, drowsiness, difficulty breathing, seizures, low or high blood pressure.

**If you forget to take a dose of ALONZA:**

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 **ALONZA** at the next regularly scheduled time. Do not take a double dose to make up for forgotten individual doses.

**4. Possible side effects**

**ALONZA** can cause side effects.

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

If any of the following happens, stop taking **ALONZA** 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.
- Yellowing of the skin and eyes, also called jaundice or hepatitis.

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

- 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 (pain, tenderness and swelling in the area of the blockage)
- Pneumonia (lung infection causing difficulty in breathing, coughing associated with fluids or phlegm and fever)
- 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 cause an electrolyte imbalance in your body (nausea, vomiting, headache, fruity smell on 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.

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Other side effects:

Frequent:

- Increased appetite, weight gain.
- Swelling of your face, legs, feet, arms or body due to water retention.
- High cholesterol or fat levels in your blood
- Drowsiness, dizziness, restlessness
- Parkinsonism (tremor, slow movements, rigidness and unstable posture)
- Hallucinations (seeing, hearing or sensing things that are not real).
- Difficult, uncontrolled movements
- Changes in the way you walk or falling easily
- Low blood pressure when you get up too quickly
- Constipation, dry mouth.
- Skin rash
- Joint pain
- Decreased sexual drive (libido), trouble getting an erection.
- Abnormal weakness or tiredness, fever
- 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).

Less frequent:

- High blood sugar (increased thirst and urination).
- Muscle cramps
- Loss of memory, difficulty speaking, trouble articulating words or stuttering, uncomfortable sensation in legs (restless leg syndrome)
- Nose bleeds

- Pain of your stomach area, pancreatitis (pain of your stomach are radiating to your back).
- Severe sensitivity of your skin to sunlight, loss of hair
- Breakdown of muscle tissue (muscle pain, tenderness or swelling, nausea, vomiting and confusion).
- Changes in urination
- Changes in your menstrual cycle (period) or painful menstrual cycles, persistent, painful erection
- Symptoms of withdrawal once you stop taking **ALONZA** (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.

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. 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 **ALONZA.**

## 5. How to store ALONZA

- Store at or below 25 ºC,
- Do not remove the tablets from the container until required for use.
- **KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.**
- Do not use the tablets after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

**What ALONZA contains:**

The active substance is olanzapine.

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The other ingredients are: Lactose monohydrate, cellulose microcrystalline (Flocel 101), crospovidone (Polyplasdone XL-10), hydroxypropylcellulose (Klucel EXF), hydroxypropylcellulose (Klucel EF), magnesium stearate

*Seal coating:* Hypromellose E5

*Film coating:* Opadry 13B58802 White

**What ALONZA looks like and contents of the pack**

Silver aluminium/aluminium blister strips containing 14 tablets.

Pack size: 28 (2 blisters strips x 14 tablets per blister strip).

**ALONZA 2,5 mg:** White to off-white, round, biconvex, film coated tablets, plain on both sides.

**ALONZA 5 mg:** White to off-white, round, biconvex, film coated tablets, debossed with ‘O1’ on one side and plain on other side.

**ALONZA 10 mg:** White to off-white, round, biconvex, film coated tablets, debossed with ‘O3’ on one side and plain on other side.

**HOLDER OF CERTIFICATE OF REGISTRATION**

Accord Healthcare (Pty) Ltd

Tuscany Office Park, Building 2

6 Coombe Place

Rivonia

Johannesburg

South Africa

**This leaflet was last revised in**

1 June 2021
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**Registration number**

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**ALONZA 5 mg:** 49/2.6.5/0036

**ALONZA 10 mg:** 49/2.6.5/0037


Initials: