Clean Proposed Patient Information Leaflet for Medicines for Human Use:

AKLID

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

AKLID film coated tablets

Please read this leaflet carefully before you start taking AKLID.

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

Active ingredient

Each film coated tablet contains 600 mg linezolid.

Inactive ingredients

Colloidal silicon dioxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, Opadry White (containing hypromellose, macrogol and titanium dioxide), poloxamer, povidone, sodium starch glycolate and talc.

Contains sugar: lactose monohydrate.

2. WHAT AKLID IS USED FOR

AKLID is an antibiotic of the oxazolidone group that works by stopping the growth of certain bacteria. It is used to treat the following bacterial infections: pneumonia, skin and soft tissue infections and vancomycin-resistant infections. Your doctor will decide if your infection can be treated with **AKLID**.

3. BEFORE YOU ARE GIVEN AKLID

Do not take AKLID:

- If you are hypersensitive (allergic) to linezolid or any of the other ingredients of **AKLID** (see WHAT AKLID CONTAINS).
- If you are taking or have taken within the last 2 weeks any medicines known as monoamine oxidase inhibitors, such as phenelzine, isocarboxazid, selegiline or moclobemide (used to treat depression or Parkinson's disease).
- If you have uncontrolled high blood pressure.
- If you have phaeochromocytoma (a rare tumour affecting your adrenal glands).
- If you have been diagnosed with a carcinoid (a tumour occurring in the glands of your intestines).
- If you have thyrotoxicosis (an excessive quantity of thyroid hormones in your bloodstream).
- If you have bipolar depression (mental disorder characterised by periods of elevated mood and periods of depression).
- If you have schizoaffective disorder (a condition in which you experience a combination of schizophrenia symptoms, such as hallucinations or delusions, and mood disorder symptoms, such as mania or depression).
- If you experience acute confusional states (a period of reversible confusion).
- If you are taking serotonin reuptake inhibitors, tricyclic antidepressants, or serotonin-norepinephrine reuptake inhibitors (SNRis) (medicine used to treat depression).

- If you are taking serotonin S-HT_1 receptor agonists (triptans) (medicine used to treat migraine or cluster headaches).
- If you are taking adrenergic bronchodilators (medicine used to help open your air passages, used to treat asthma and chronic bronchitis).
- If you are taking pseudoephedrine or phenylpropanolamine (medicine used to treat nasal and sinus congestion).
- If you are taking vasopressor agents, such as epinephrine (adrenaline), norepinephrine (noradrenaline) (medicine used to treat low blood pressure).
- If you are taking dopaminergic agents, such as dopamine or dobutamine (medicine used to heart problems).
- If you are taking pethidine (medicine used to treat pain).
- If you are taking buspirone (medicine used to treat the symptoms of anxiety).
- If you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding**).

Take special care with AKLID:

Make sure you contact your doctor if you have any other medical problems, especially:

- If you have severe, persistent and/or bloody diarrhoea while or after taking **AKLID**.
- If recurrent signs of nausea, vomiting, unexplained acidosis or a low bicarbonate level occur while taking **AKLID**, you may have lactic acidosis.
- If you have eye problems e.g. changes in colour vision, blurred vision or loss of vision while taking **AKLID**. The use of **AKLID** can cause optic neuropathy (damage to your eyes).
- If you experience any feeling of numbness in your hands and feet, or you have a burning sensation or pain. The use of **AKLID** can cause damage to your nerves (peripheral neuropathy).
- If you have a very bad infection that does not want to heal or is taking a very long time to get better.

- If you have a tendency towards seizures.
- If you previously had bone marrow depression or if you are unusually tired or weak, you have fevers, chills, a cough or hoarseness, lower back pain or painful and difficult urination. These may be signs of bone marrow depression and can occur in patients taking **AKLID** for longer than 28 days.
- If you are receiving **AKLID** for longer than 28 days.
- If you have porphyria (a hereditary condition).
- If you are consuming foods that are rich in tyramine, such as matured cheese, products containing yeast, undistilled alcoholic beverages or soy sauce.
- If you have severe kidney problems.
- If you have a liver problem.

Taking AKLID with food or drink:

AKLID may be taken with or without food. **AKLID** should not be taken with foods that are rich in tyramine, such as matured cheese, food containing yeast, undistilled alcoholic beverages or soy sauce. Contact your doctor if you experience a throbbing headache after eating a meal.

Pregnancy and breastfeeding:

Do not take **AKLID** if you are pregnant, planning to become pregnant or breastfeeding your baby.

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

Driving and using machinery:

AKLID can cause side effects, such as dizziness, low blood pressure or blurred vision. Do not drive a vehicle or operate machinery until you know how **AKLID** affects you.

Important information about some of the ingredients of AKLID:

AKLID contains lactose. If you have been told by your doctor that you have an intolerance to some sugars (that you cannot digest some sugars), contact your doctor before taking **AKLID**.

Taking other medicines with AKLID:

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

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

- Monoamine oxidase inhibitors, such as phenelzine, isocarboxazid, selegiline or moclobemide (used to treat depression or Parkinson's disease) (see **Do not take AKLID**).
- Medicine that causes bone marrow suppression (e.g. chemotherapy).
- Serotonergic medication (e.g. antidepressants and psychiatric medication, anti-anxiety medication, certain medications used for nausea and vomiting and anti-migraine medicines).
- Other antibiotic medication.
- Medication that influence the function of adrenaline (adrenergic medication).
- Dextromethorphan (used to treat coughing).
- Food containing tyramine (e.g. matured cheese, yeast extracts, undistilled alcoholic beverages and fermented soybean products such as soy sauce).
- Pethidine (used to treat pain) (see **Do not take AKLID**).
- Rifampicin (TB medication).

4. HOW TO TAKE AKLID

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

The usual dose is 600 mg twice daily. Your doctor will tell you how long your treatment with **AKLID** will last.

If you have the impression that the effect of **AKLID** is too strong or too weak, talk to your doctor or pharmacist.

If you take more AKLID than you should:

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

Treatment is supportive and haemodialysis may help to remove some **AKLID** from your body.

If you forget to take AKLID:

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 AKLID at the next regularly scheduled time.

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

5. Possible side effects

AKLID can have side effects.

Not all side effects reported for **AKLID** are included in this leaflet. Should your general health worsen while taking **AKLID**, please consult your doctor, pharmacist or other healthcare professional.

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat which may cause difficulty in swallowing or breathing.
- Rash or itching, hives, blisters and peeling of your skin, fever.
- Fainting.
- Yellowing of the skin and eyes, also called jaundice.

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

- Signs of recurrent infections such as fever or sore throat.
- Severe, persistent and/or bloody diarrhoea.
- Eye problems such as blurred vision, loss of vision, changes in colour vision or changes in your visual field.
- If you are unusually tired or weak, you have fevers, chills, a cough or hoarseness, lower back pain or painful and difficult urination. These may be signs of bone marrow depression.
- Lactic acidosis (e.g. recurrent signs of nausea, vomiting, unexplained acidosis or a low bicarbonate level).
- Severe skin disorders such as Stevens-Johnson syndrome (severe, painful blistering skin rash).
- Pancreatitis (associated with a severe upper stomach burning pain radiating to your back, nausea and vomiting).
- Serotonin syndrome (confusion, agitation, restlessness, headache, changes in blood pressure, nausea, vomiting, diarrhoea, increased heart rate, loss of muscle

coordination, twitching and sweating).

- Seizures (fits).

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

Tell your doctor if you notice any of the following:

- Nausea (feeling sick) and vomiting (being sick).
- Constipation, stomach pain and discomfort, cramps, indigestion or feeling bloated.
- Metallic taste, dry mouth or oral thrush.
- Increased thirst.
- Discolouration of your tongue or teeth.
- Headache, dizziness and seizures.
- High blood pressure, low blood pressure (e.g. light-headedness and dizziness) and high blood sugar.
- Feeling of numbness in your hands and feet, or a burning sensation or pain (peripheral neuropathy (damage to your nerves) or paraesthesia).
- Loss of sensation on touch.
- Difficulty sleeping (insomnia).
- Itchiness and inflammation of the skin (dermatitis) and increased sweating.
- Increased urination.
- Vaginal thrush and vaginal inflammation.
- Thrush and other fungal infections.
- Chills.
- Tiredness and ringing sound in your ears (tinnitus).
- Abnormal blood and other test results.

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

6. STORING AND DISPOSING OF AKLID

- Store at or below 30 °C.
- Do not remove from outer carton until required for use.
- **STORE ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.**
- Do not use after the expiry date printed on the label or 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 AKLID

A cardboard box containing silver aluminium / aluminium blister strips containing 1x6, 2x14 or 3x10 film coated tablets and a package insert, or

A cardboard box containing white PVC/PE/PVDC / silver aluminium foil blister strips, containing 1x9, 1x10, 2x14 or 3x10 film-coated tablets and a package insert, or

A cardboard box containing a white HDPE bottle, with a child resistant screw cap and mounted desiccant containing 10 or 30 film coated tablets and a package insert.

Pack sizes: 6, 9, 10, 28 and 30 film coated tablets.

8. IDENTIFICATION OF AKLID

White, oval biconvex tablets.

9. REGISTRATION NUMBER

48/20.1.1/0949

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road Parktown,

Johannesburg, 2193

South Africa.

11. DATE OF PUBLICATION

02 June 2017

Access to the corresponding Professional Information and Afrikaans Patient Information Leaflet

Professional Information and Afrikaans Patient Information Leaflet for this medicine is available on the following URL: https://austell.co.za/product-info/

Austell Pharmaceuticals (Pty) Ltd

Tel: +27 11 611 1400 or +27 860 287 835