PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

LINEZOLID TEVA 600 (film-coated tablet)

Read all of this leaflet carefully before you start taking LINEZOLID TEVA 600:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **LINEZOLID TEVA 600** 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 LINEZOLID TEVA 600 CONTAINS:

- Each Linezolid Teva 600 tablet contains 600 mg linezolid.

The other ingredients are:

Tablet core: Croscarmellose sodium, crospovidone, hydroxypropylcellulose, lactose monohydrate, magnesium stearate, maize starch, Starlac® (composed of lactose monohydrate and maize starch).

Film-coating: Opadry Y1-7000H White consisting of hypromellose, macrogol 400, titanium dioxide.

Contains lactose monohydrate.

2. WHAT LINEZOLID TEVA 600 IS USED FOR:

Linezolid Teva 600 is an antibiotic that works by stopping the growth of certain bacteria (germs) that cause infections. It is used to treat pneumonia and some infections in the skin or under the skin.

3. BEFORE YOU TAKE LINEZOLID TEVA 600:

Do not take LINEZOLID TEVA 600:

- If you are hypersensitive (allergic) to linezolid or any other ingredients of Linezolid Teva 600.
- If you are on monoamine oxidase inhibitor (MAOI) treatment or have taken a MAOI within the last two weeks (such as phenelzine, isocarboxazid, selegiline, moclobemide). MAOI's may be used to treat depression or Parkinson's disease.
- If you have a tumour of the adrenal glands (phaeochromocytoma) or carcinoid syndrome (caused by tumours of the hormone system with symptoms of diarrhoea, flushing of the skin, wheezing).
- If you suffer from manic depression, schizoaffective disorder (a mental illness with symptoms of two different conditions; schizophrenia (delusions and hallucinations) and a mood disorder which causes extremes of high (manic) and low (depressive) moods), mental confusion or other mental problems.
- If you are taking any of the following medicines:
  - Antidepressants known as tricyclics or SSRI's (selective serotonin reuptake inhibitors).
  - Medicines used to treat migraines such as the triptans (sumatriptan and zolmitriptan).
  - Medicines used to treat sudden, severe allergic reactions such as adrenaline (epinephrine).
  - Medicines which increase your blood pressure, such as noradrenaline (norepinephrine), dopamine and dobutamine.
  - Medicines used to treat severe pain, such as pethidine.
  - Medicines used to treat anxiety disorders, such as buspirone.
- If you are pregnant or breastfeeding your baby (see ''Pregnancy and breastfeeding'').

Take special care with LINEZOLID TEVA 600:

Tell your doctor if you:

- Have high blood pressure
- Have been diagnosed with an overactive thyroid
- Are taking any medicines (see ''Using other medicines with Linezolid Teva 600'')
- Are taking anti-depressants such as selective serotonin reuptake inhibitors (SSRIs). Serotonin syndrome (symptoms include headache, confusion, abnormally high body temperature, muscle twitching and incoordination) can occur when Linezolid Teva 600 and these antidepressants are taken together.

- Have diarrhoea or if you develop diarrhoea while using Linezolid Teva 600. If this becomes severe or persistent or you notice that your stools contain blood or mucus, you should stop taking Linezolid Teva 600 immediately and consult your doctor. In this situation, you should not take medicines that stop or slow bowel movement.
- Are tired, have a loss of appetite, nausea, vomiting, stomach pain, and weight loss. These may be signs of a serious condition (lactic acidosis) and you may need medical help.
- Develop problems with your vision such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted. Your doctor should monitor your eyesight if you take Linezolid Teva 600 for more than 28 days.
- Develop loss of sensitivity in your arms or legs or a sensation of tingling or pricking in your arms or legs.

Tell your doctor before you take Linezolid Teva 600 if you:

- bruise and bleed easily
- are anaemic
- are prone to getting infections
- have a history of seizures
- have kidney problems particularly if you are on dialysis
- have liver problems
- have porphyria, an inherited blood disorder which causes severe stomach pain, confusion, breathing problems, skin sensitivity and pain, skin redness and swelling as well as blisters.

Taking LINEZOLID TEVA 600 with food and drink:

Linezolid Teva 600 can be taken with or without food.

You should avoid consuming large amounts of foods and drink that are rich in tyramine including matured cheeses, yeast extracts (e.g. Oxo, Bovril, Marmite), undistilled alcoholic drinks (particularly draught beer and wine) and fermented soya bean products (e.g. soy sauce), as this can cause a dangerous rise in blood pressure.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or healthcare professional for advice.

Linezolid Teva 600 cannot be used during pregnancy and breastfeeding as safety has not been proven.

Driving and using machinery:

Linezolid Teva 600 may make you feel dizzy or experience problems with your vision. If this happens, do not drive or operate any machinery. Remember that if you are unwell your ability to drive or operate machinery may be affected.

Important information about some of the ingredients of LINEZOLID TEVA 600:

Linezolid Teva 600 contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Linezolid Teva 600.

Using other medicines with LINEZOLID TEVA 600:

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

- If you are taking or have taken within the last 2 weeks the following medicines, Linezolid Teva 600 must not be taken:
  - Monoamine oxidase inhibitors (MAOIs, for example phenelzine, isocarboxazid, selegiline, moclobemide). These may be used to treat depression or Parkinson's disease.
- The use of Linezolid Teva 600 with decongestant cold or flu remedies such as pseudoephedrine and phenylpropanolamine hydrochloride as well as dopamine and dobutamine used mostly in hospital may lead to an increase in your blood pressure.
- The use of Linezolid Teva 600 in combination with medicines known as serotonergics used as anti-depressants may lead to symptoms such as a very high fever and delirium.

- Rifampicin (an antibiotic used for the treatment of TB).
- Medicines used to treat asthma such as salbutamol, terbutaline, fenoterol.
- Antidepressants known as tricyclic antidepressants or SSRIs (selective serotonin reuptake inhibitors) for example amitriptyline,citalopram , clomipramine, dosulepin, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine, sertraline.
- Medicines used to treat migraine such as sumatriptan and zolmitriptan.
- When Linezolid Teva 600 is taken with pethidine (an opioid analgesic) serotonin syndrome (headache, confusion, abnormally high body temperature, muscle twitching and incoordination) can occur and requires immediate medical attention.

4. HOW TO TAKE LINEZOLID TEVA 600:

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

Always take Linezolid Teva 600 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Linezolid Teva 600 tablets should be taken two times per day by mouth but your doctor will determine your dose depending on the type of infection.

If you are undergoing haemodialysis you should take your dose of Linezolid Teva 600 after such treatment.

Your doctor will tell you how long your treatment with Linezolid Teva 600 will last.

If you have the impression that the effect of Linezolid Teva 600 is too strong or too weak, tell your doctor or pharmacist.

Do not stop treatment early as Linezolid Teva 600 is an antibiotic and you have to complete the course to prevent resistance of the bacteria to the medicine.

If you take more LINEZOLID TEVA 600 than you should:

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of LINEZOLID TEVA 600:

If you forget to take a dose, take it as soon you remember. Do not take a double dose to make up for forgotten individual doses

5. POSSIBLE SIDE EFFECTS:

Linezolid Teva 600 can have side effects.

Not all side effects reported for Linezolid Teva 600 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Linezolid Teva 600, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking Linezolid Teva 600 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Skin reactions such as red sore skin and flaking (dermatitis), rash, itching, or swelling, of the tongue, throat, face and neck.
- Shortness of breath and wheezing.
- Serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome and Toxic epidermal necrolysis).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Linezolid Teva 600. You may need urgent medical attention or hospitalisation.

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

- Deep and rapid breathing, drowsiness, nausea, vomiting and stomach pain (Lactic acidosis).
- Headache, confusion, abnormally high body temperature, muscle twitching and incoordination (Serotonin syndrome).
- Weakness, numbness or paralysis in your face, arm or leg, typically on one side of your body (Transient ischaemic attack).
- Blurred vision

- Decrease in number of red blood cells, white blood cells, and blood platelets. The decrease in the number of blood cells can cause you to feel more tired than usual, bruise easily and there may be an increase in the time for bleeding to stop. A decrease in the white blood cell count may also cause you to be more susceptible to infections.
- Convulsions (fits)
- Changes in the heart rate (fast heart beat)
- Upper abdominal swelling and pain that radiates into the back as well as nausea, vomiting, fever and a fast heart beat which are symptoms of inflammation of the pancreas
- Severe diarrhoea containing blood and/or mucus which in very rare circumstances may develop into complications that are life-threatening (Pseudomembranous colitis).

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

The following side effects have been reported frequently:

- Thrush or fungal infection.
- Headache.
- Metallic taste, abdominal pain, cramps, diarrhoea, nausea, vomiting.
- Abnormalities in certain blood tests.

The following side effects have been reported less frequently:

- Chills, fatigue, fever
- Dizziness, reduced sense of touch, sleeplessness, pins and needles.
- Ringing in ears.
- Constipation, dry mouth, heart burn, inflammation of the stomach lining, increased thirst, inflammation in the mouth, tongue discolouration or disorder, oral thrush, sense distortion.
- High or low blood pressure. Look out for symptoms that include headache, dizziness, blurred vision, chest pain and shortness of breath, fainting, confusion, nausea which are all signs of changes in your blood pressure.

- Vulvovaginal disorder. Inflammation of the vagina or genital area in women.
- Increased urination.

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

6. STORING AND DISPOSING OF LINEZOLID TEVA 600:

Store at or below 25 °C.

Keep the tablets in the blister strip and the blister strip in the outer carton until required for use.

Do not store in a bathroom

Do not use after the expiry date stated on the label / carton / bottle

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

7. PRESENTATION OF LINEZOLID TEVA 600:

Tablets are packed in aluminium blister packs inside a cardboard box.

- PVC / PVdC transparent and Aluminium blister packs
- OPA/Aluminium/PVC and Aluminium (push through) blister packs

Pack sizes: 10, 20, 28, 30, 60, 90, 100 tablets per outer carton or hospital pack of 50 x 1.

8. IDENTIFICATION OF LINEZOLID TEVA 600:

A white, film-coated modified capsule shaped tablet, debossed with “600” on one side. The other side is scored.

9. REGISTRATION NUMBER:

48/20.1.1/1315

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Teva Pharmaceuticals (Pty) Ltd

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Magwa Crescent West

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11. DATE OF PUBLICATION:

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