335 mm

380 mm

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ELTURIN 600 mg (Film-coated tablet)
Linezolid
Sugar free

Read all of this leaflet carefully before you start taking ELTURIN 600
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ELTURIN 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.

What is in this leaflet

1. What **ELTURIN 600** is and what it is used for
2. What you need to know before you take **ELTURIN 600**
3. How to take **ELTURIN 600**
4. Possible side effects
5. How to store **ELTURIN 600**
6. Contents of the pack and other information

1. What ELTURIN 600 is and what it is used for

ELTURIN 600 contains linezolid which is an antibiotic that works by stopping the growth of certain bacteria (germs) that causes infections. **ELTURIN 600** is used for treating bacterial infections against which linezolid is active.

2. What you need to know before you take ELTURIN 600

Do not take ELTURIN 600
- If you are hypersensitive (allergic) to linezolid or to any of the ingredients of **ELTURIN 600**.
- If you are breastfeeding your baby; this is because **ELTURIN 600** passes into breast milk and could affect the baby.
- If you are suffering from conditions such as high blood pressure, tumor of the adrenal glands, diarrhoea, skin redness, breathing problem, overactive thyroid gland, mood disorders, mental disorders such as hallucinations or delusions and disorder of decreased attention or awareness.
- If you are taking or you have taken in the last two weeks, medicines used to treat depression known as monoamine oxidase inhibitors (e.g. phenelzine, isocarboxazid).
- If you are taking medicines used to treat depression such as serotonin re-uptake inhibitors or tricyclic antidepressants. There are many examples of these medicines, including amitriptyline, citalopram, clomipramine, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine, sertraline.
- If you are taking medicines used to treat migraine headache such as sumatriptan and zolmitriptan (serotonin 5-HT1 receptor agonists (triptans)).
- If you are taking medicines used to treat low blood pressure and heart failure such as noradrenaline (norepinephrine), dopamine and dobutamine.
- If you are taking decongestant cold or flu remedies containing medicines such as pseudoephedrine or phenylpropanolamine.
- If you are taking medicines used to treat moderate to severe pain, such as pethidine.
- If you are taking medicines used to treat anxiety disorders such as buspirone.

Warnings and precautions
Take special care with **ELTURIN 600**:
- If you have high blood pressure and whether or not you are taking medicines for this.
- If you been diagnosed with an overactive thyroid.
- 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, mental confusion or other mental problems.
- If you have liver problems or kidney problems particularly if you are on dialysis.
- If you are taking treatment for depression with serotonin re-uptake inhibitors as combination of **ELTURIN 600** with these medicines may lead to symptoms such as high body temperature, agitation, increased reflexes, tremor, sweating, dilated pupils, and diarrhoea.
- If you have been diagnosed with a severe infection related to a central venous catheter (a long, thin, flexible tube used to give medicines, fluids, nutrients, or blood products over a long period of time, inserted in the arm or chest through the skin into a large vein).
- Tell your doctor if you suffer from diarrhoea, abdominal cramps, bloody stools with accompanying fever after taking **ELTURIN 600**. You should not take medicines that stop or slow down bowel movement.
- **ELTURIN 600** may reduce blood cell counts i.e. red blood cells, white blood cells and platelets. Your doctor will monitor your blood cell count if bleeding is observed after taking **ELTURIN 600** and if you are taking **ELTURIN 600** for more than two weeks. Tell your doctor if you notice the following:
  - Unexplained bleeding or bruising, which may be due to changes in the numbers of certain cells in the blood which may affect blood clotting or lead to anaemia).
  - Changes in numbers of certain cells in the blood which may affect your ability to fight infection. Some signs of infection include: fever, sore throat, mouth ulcers and tiredness.
- **ELTURIN 600** may cause problems with your vision such as blurred vision, difficulty in distinguishing colour, difficulty in seeing detail or if your field of vision becomes restricted. Tell your doctor if you have such symptoms. Your doctor may prescribe regular eye tests if you are taking **ELTURIN 600** for three months or longer.
- **ELTURIN 600** may cause numbness or weakness of the arms and legs. Tell your doctor if you are receiving treatment for tuberculosis (TB) infection. Taking **ELTURIN 600** with your TB medicines may increase the risk of experiencing weakness, numbness and pain in the arms and legs.
- **ELTURIN 600** may cause lactic acidosis (too much acid in the blood). Tell your doctor if you experience deep, rapid breathing, drowsiness and symptoms such as nausea, vomiting and stomach pain, which might indicate the development of lactic acidosis.
- Tell your doctor if you have a history of seizures (fits) as **ELTURIN 600** may cause seizures.
- Treatment with **ELTURIN 600** may cause a superinfection (an infection occurring after or on top of an earlier infection).
- Avoid eating large amounts of mature cheese, yeast extracts, or soya bean extracts e.g., soy sauce and drinking alcohol, especially draught beers and wine. This is because **ELTURIN 600** may react with a substance called tyramine which is naturally present in some foods. This interaction may cause an increase in your blood pressure.
- **ELTURIN 600** should not be taken for longer than 28 days as the safety and effectiveness has not been established beyond 28 days.

Other medicines and ELTURIN 600
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).
- Tell your doctor if you are taking, or have recently taken any other medicines.
- Phenytoin (used to treat seizure or fits).
- Pseudoephedrine or phenylpropanolamine (used to treat cold or flu).
- Dopamine, dobutamine and noradrenaline (medicines which increase blood pressure).
- Dextromethorphan (used to treat cough).
- Serotonin re-uptake inhibitors, tricyclic antidepressants (used to treat depression).
- Rifampicin (antibiotic used to treat tuberculosis).
- Warfarin (medicine that stops blood clotting).

ELTURIN 600 with food and drink and alcohol
ELTURIN 600 can be taken either before, during or after a meal.
Do not eat large amounts of mature cheese, yeast extracts, fermented soya bean products such as soy sauce and undistilled alcoholic beverages (see Warnings and precautions above)

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **ELTURIN 600**.
- Do not take **ELTURIN 600** if you are pregnant.
- Do not breastfeed if you are taking **ELTURIN 600** because it passes into breast milk and could affect the baby.

Driving and using machines
ELTURIN 600 may make you feel dizzy or experience problems with your vision. Do not drive or operate machinery if you experience these side effects.

3. How to take ELTURIN 600

- Do not share medicines prescribed for you with any other person.
- The usual dose of **ELTURIN 600** is one film-coated tablet, swallowed with water, twice daily (every twelve hours), taken with or without food.
- Always take **ELTURIN 600** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- A course of treatment usually lasts 10 to 14 days, but can last up to 28 days. The safety and effectiveness of **ELTURIN 600** have not been established for treatment periods longer than 28 days.
- Your doctor will tell you how long your treatment with **ELTURIN 600** will last. Do not stop treatment early.
- If you have the impression that the effect of **ELTURIN 600** is too strong or too weak, tell your doctor or pharmacist.
- Stay under a healthcare provider's care when taking **ELTURIN 600**. Do not change your treatment or stop treatment without first talking with your healthcare provider.

If you take more ELTURIN 600 than you should
Seek emergency medical attention if you think you have taken too much of **ELTURIN 600**.
In the event of overdosage consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.

If you forget to take ELTURIN 600
If you forget to take a dose, take it as soon as you remember, and then continue as before.
Do not take a double dose to make up for forgotten individual doses.

If you stop taking ELTURIN 600
Do not stop taking **ELTURIN 600** unless your doctor tells you to stop treatment.
If you have any further questions on the use of **ELTURIN 600**, ask your doctor or pharmacist.
The time you will take **ELTURIN 600** for depends on your infection.
It is important that you complete the course of treatment even if you begin to feel better after a few days. If you stop taking **ELTURIN 600** too soon your infection may not be completely cured and the infection may return or your condition may get worse. The bacteria causing your infection may become resistant to **ELTURIN 600**.
The recommended dose and duration of treatment should not be exceeded.

4. Possible side effects

ELTURIN 600 can have side effects.
Not all side effects reported for **ELTURIN 600** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **ELTURIN 600**, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, stop taking **ELTURIN 600** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Sudden signs of allergy – including skin rash, itching or hives; swelling of the face, lips or tongue, shortness of breath or difficulty breathing.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- Skin reactions such as red sore skin and flaking (dermatitis), rash, itching, or swelling, particularly around the face and neck. This may be the sign of an allergic reaction and it may be necessary for you to stop taking **ELTURIN 600**.
- Vision problems such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.
- Severe diarrhoea containing blood and/or mucus (antibiotic associated colitis including pseudomembranous colitis), which in less frequent circumstances may develop into complications that are life-threatening.
- Recurrent nausea or vomiting, abdominal pain or rapid breathing (signs of lactic acidosis).
- Kidney failure. Symptoms of kidney failure are due to the build-up of waste products and excess fluid in the body that may cause weakness, shortness of breath, lethargy, swelling, and confusion.
- Inflammation of the pancreas. Symptoms include upper abdominal pain, nausea and vomiting.
- Fits or seizures.

These are all serious side effects. You may need urgent medical attention.
Tell your doctor if you notice any of the following:
Frequent side effects:
- Headache, Metallic taste in mouth.
- Diarrhoea, nausea, vomiting, abdominal pain, cramps or distension.
- Fungal infection, fungal/yeast infection of vagina and oral cavity.
- Difficulty in sleeping.
- Skin itching and rash.
- Changes in some blood test results including those measuring your kidney or liver function or blood sugar levels.

Less frequent side effects:
- Anaemia with symptoms of tiredness, headaches, being short of breath when exercising, dizziness and looking pale.
- Frequent infections such as fever, severe chills, sore throat or mouth ulcers (signs of leukopenia or neutropenia (reduction of white blood cells)).
- Pancytopenia (a rare type of anaemia in which the red blood cells, white blood cells and platelets are all reduced in number).
- Thrombocytopenia (bleeding or bruising more easily than normal).
- Reduction in bone marrow activity.
- Increased number of some white blood cells (eosinophils).
- Sideroblastic anaemia (anaemia due to formation of ringed red blood cells).
- Swelling beneath the skin's surface.
- Severe allergic reactions.
- High blood sugar.
- Hyponatraemia (decreased blood sodium level).
- Dizziness.
- Loss of sensitivity in your arms or legs or a sensation of tingling or pricking in your arms or legs.
- Weakness, numbness and pain from nerve damage, usually in the hands and feet.
- Sudden, violent, irregular movement of the body.
- Problems with vision such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted, loss of vision.
- Ringing in the ears (tinnitus).
- Improper beating of the heart.
- Increased or decreased blood pressure.
- Temporary disturbance of blood flow to the brain causing short term symptoms such as loss of vision, leg and arm weakness, slurring of speech and loss of consciousness.
- Formation of blood clot in vein resulting in inflammation.
- Constipation, dry mouth, stomach pain and inflammation, irritation, or erosion of the lining of the stomach, increased thirst, inflammation of the mouth and tongue, tongue discolouration, superficial tooth discolouration, loose stools.
- Skin problems as skin rash, skin inflammation, swelling of skin and severe skin reactions.
- Increased sweating.
- Hair loss.
- Increase in creatinine level.
- Urinating more than normal.
- Inflammation of the vagina or genital area in women.
- Chills, fatigue, fever, localised pain.

Less frequent side effects that may show up in laboratory tests are:
- Proteins in the urine increase in enzymes, increased blood urea nitrogen levels.
- Changes in salts (sodium, calcium, chloride, potassium, bicarbonate) in the blood.
- Increased or decreased non-fasting glucose.
- Changes in blood cell count such as increased reticulocyte count (immature red blood cells); decreased neutrophils (type of white blood cells).
- Changes in numbers of certain cells or component in the blood such as white blood cells, haemoglobin, red blood cells count and platelets.

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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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 **ELTURIN 600**.

5. How to store ELTURIN 600

Store all medicines out of reach of children.
Store at or below 30 °C. (Room temperature)
Store in the original package.
Keep the strip in the carton until required for use
Protect from light and moisture.
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 (e.g. toilets).

6. Contents of pack and other information

What ELTURIN 600 contains
- The active substances are Linezolid 600 mg.
- The other ingredients are colloidal anhydrous silica, crospovidone, hydrogenated polyoxyl castor oil, magnesium stearate, microcrystalline cellulose, povidone (K 30) and sodium starch glycolate. The film coating contains hypromellose, macrogol 6000, purified talc and titanium dioxide.

What ELTURIN 600 looks like and contents of the pack
White to off-white, capsule shaped, biconvex film-coated tablets with deep score on both sides.

Blister or strip pack:
Tablets are packed in a blister pack of hard tempered aluminium foil and PVC film or in a strip pack of Aluminium /Aluminium foil laminated with low - density polyethylene film and further packed in an outer carton in packs of 10, 20, 30 or 100 tablets.
Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration and Manufacturer
MACLEODS PHARMACEUTICALS SA (PTY) LTD.
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Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www/macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 1169.

ELTURIN 600
PM03917002

335 mm

280 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS : S4

ELTURIN 600 (filmbedekte tablette)
Linesolied
Suikervry

Lees hierdie hele inligtingstuk noukeurig deur, voordat u begin om ELTURIN 600 te gebruik
- Hou hierdie inligtingstuk. U mag dit dalk weer moet lees.
- Indien u nog vrae het, vra asseblief vir u dokter of u apteker.
- **ELTURIN 600** is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hul skaad, selfs al is hulle simptome dieselfde as u s'n.

Wat is in hierdie inligtingstuk

1. Wat **ELTURIN 600** is en waarvoor dit gebruik word
2. Wat u behoort te weet voordat u **ELTURIN 600** neem
3. Hoe om **ELTURIN 600** te neem
4. Moontlike newe effekte
5. Hoe om **ELTURIN 600** te berg
6. Inhoud van die pak en ander inligting

1. Wat ELTURIN 600 is en waarvoor dit gebruik word

ELTURIN 600 bevat linesolied wat 'n antibiotikum is wat werk deur die groei van sekere bakterieë (kieme) wat infeksies veroorsaak, te stop**. ELTURIN 600** word gebruik vir die behandeling van bakteriële infeksies waarteen linesolied aktief is.

2. Wat u behoort te weet voordat u ELTURIN 600 neem

Moet nie ELTURIN 600 neem:
- Indien u hipersensitief (allergies) vir linesolied of enige van die ander bestanddele van **ELTURIN 600** is nie.
- Indien u, u baba borsvoed, omrede **ELTURIN 600** in borsmelk oorgaan en die baba kan beïnvloed.
- Indien u ly aan toestande soos hoë bloeddruk, gewasse in die byniere, diarree, velrooiheid, asemhalingsprobleme, ooraktiewe skildklier, gemoedsversteurings, geestesversteurings soos hallusinasies of wanbeelde en versteuring van aandag of bewustheid.
- Indien u medisyne wat depressie behandel, bekend as monoamienoksidase-inhibeerders (bv. fenelsien, isokarboksasied), gebruik of die afgelope twee weke gebruik het nie.
- Indien u medisyne gebruik, bekend as serotonienheropname-inhibeerders of trisikliese antidepressante. wat depressie behandel, Daar is baie voorbeelde van hierdie medisyne, insluitend amitriptillien, sitalopram, klomipramien, doksepien, fluoksetien, fluvoksamien, imipramien, lofepramien, paroksetien, sertralien.
- Indien u medisyne gebruik soos sumatriptaan en zolmitriptaan (serotonin 5-HT1 reseptoragoniste (triptane)) om migraine hoofpyne te behandel.
- Indien u medisyne soos noradrenalien (norepinefrien), dopamien en dobutamien gebruik om lae bloeddruk te behandel.
- Indien u dekongestante verkoue- of griepmiddels neem, wat medisyne soos pseudoefedrien of fenielpropanolamien bevat.
- Indien u medisyne soos petidien neem om matige tot erge pyn te verlig.
- Indien u medisyne soos buspiroon neem, wat gebruik word om angsversteurings te behandel.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met **ELTURIN 600:**
- Indien u hoë bloeddruk het en of u medisyne hiervoor neem al dan nie.
- Indien u gediagnoseer is met 'n ooraktiewe tiroïed.
- Indien u 'n gewas in die byniere (feochromositoom) of karsinoïedsindroom het (wat veroorsaak word deur gewasse in die hormoonstelsel met simptome van diarree, blosing van die vel, fluitende asemhaling).
- Indien u ly aan maniese depressie, skiso-affektiewe versteuring, geestelike verwarring of ander geestelike probleme.
- Indien u lewerprobleme of nierprobleme het, veral as u op dialise is.
- Indien u behandeling met serotonienheropname-inhibeerders vir depressie ontvang, kan die kombinasie van **ELTURIN 600** met hierdie medisyne lei tot simptome soos hoë liggaamstemperatuur, opgewondenheid, verhoogde reflekse, bewing, sweet, verwyde pupille en diarree.
- Indien u gediagnoseer is met 'n ernstige infeksie wat verband hou met 'n sentrale veneuse kateter ('n lang, dun, buigsame buis wat gebruik word om medisyne, vloeistowwe, voedingstowwe of bloedprodukte oor 'n lang tyd te gee, deur die vel van die arm of bors, in 'n groot aar in.)
- Vertel u dokter indien u ly aan diarree, maagkrampe, bloederige stoelgang met gepaardgaande koors ná inname van **ELTURIN 600.** U mag nie medisyne neem wat die beweging van die derm stop of vertraag nie.
- **ELTURIN 600** kan die bloedseltelling, dit wil sê rooibloedselle, witbloedselle en bloedplaatjies, verminder. U dokter sal die bloedseltelling monitor as die bloeding waargeneem word ná die inname van **ELTURIN 600** en as u langer as twee weke **ELTURIN 600** neem. Vertel u dokter as u die volgende opmerk:
  - Onverklaarbare bloeding of kneusplekke, wat kan wees as gevolg van veranderinge in die aantal selle in die bloed wat bloedstolling kan beïnvloed of tot bloedarmoede kan lei.
  - Veranderings in getalle van sekere selle in die bloed wat u vermoë om infeksie te beveg, kan beïnvloed. Sommige tekens van infeksie sluit in: koors, seer keel, mondsere en moegheid.
- **ELTURIN 600** kan probleme met u visie veroorsaak, soos belemmerde visie, probleme met die onderskeiding van kleur, probleme om detail te sien of as u gesigsveld beperk word. Vertel u dokter as u sulke simptome ondervind, u dokter kan gereelde oogtoetse voorskryf as u **ELTURIN 600** vir drie maande of langer neem.
- **ELTURIN 600** kan gevoelloosheid of swakheid van die arms en bene veroorsaak. Vertel u dokter as u behandeling vir tuberkulose (TB) ontvang. As u **ELTURIN 600** saam met u TB-medisyne gebruik, kan dit die risiko vir swakheid, gevoelloosheid en pyn in die arms en bene verhoog.
- **ELTURIN 600** kan melksuurlaktose veroorsaak (te veel suur in die bloed). Vertel u dokter as u diep, vinnige asemhaling, slaperigheid en simptome ervaar, soos naarheid, braking en maagpyn, wat kan dui op die ontwikkelling van melksuurasidosis.
- Vertel u dokter as u 'n geskiedenis van kolvulsies (stuipe) het, aangesien **ELTURIN 600** konvulsies kan veroorsaak.
- Behandeling met **ELTURIN 600** kan 'n superinfeksie veroorsaak ('n infeksie wat plaasvind op of na 'n vorige infeksie).
- Vermy die eet van groot hoeveelhede ryp kaas, gisekstrakte, of sojaboon-ekstrakte, bv. sojasous en alkohol, veral trekbier en wyn. Dit is omdat **ELTURIN 600** kan reageer met 'n stof genaamd tiramien wat natuurlik in sommige kosse voorkom. Hierdie interaksie kan 'n toename in u bloeddruk veroorsaak.
- **ELTURIN 600** moet nie langer as 28 dae geneem word nie, aangesien die veiligheid en effektiwiteit nie vir langer as 28 dae vasgestel is nie.

Neem van ander medisyne saam met ELTURIN 600
Vertel altyd vir u gesondheidsorgdeskundige indien u enige ander medisyne gebruik. (Dit sluit komplementêre en tradisionele medisyne in).
- Vertel u dokter indien u enige ander medisyne neem of onlangs geneem het.
- Fenitoïen (gebruik om stuipe (konvulsies) te behandel).
- Pseudoefedrien of fenielpropanolamien (gebruik om verkoue en griep te behandel).
- Dopamien, dobutamien en noradrenalien (medisyne wat bloeddruk verhoog).
- Dekstrometorfaan (word gebruik vir die behandeling van hoes)
- Serotonienheropname-inhibeerders, trisikliese antidepressante (medisyne wat gebruik word om depressie te behandel).
- Rifampisien (antibiotikum wat gebruik word vir die behandeling van tuberkulose).
- Warfarien (medisyne wat bloedstolling stop).

Neem van ELTURIN 600 saam met voedsel, vloeistof en alkohol
ELTURIN 600 kan geneem word voor, tydens of na 'n maaltyd. Moet nie groot hoeveelhede ryp kaas, gisekstrakte, gefermenteerde sojaboonprodukte soos sojasous eet en ongedistilleerde alkoholiese drankies drink nie (sien waarskuwings en voorsorgmaatreëls hierbo).

Swangerskap, borsvoeding en voortplanting
Indien u swanger is of u baba borsvoed, vra asseblief u dokter, apteker of ander gesondheidsorgdeskundige vir advies voordat u **ELTURIN 600** neem.
- Moet nie **ELTURIN 600** neem indien u swanger is nie.
- Moet nie u baba borsvoed as u **ELTURIN 600** neem nie, aangesien dit in die borsmelk uitgeskei word en die baba kan beïnvloed.

Bestuur en gebruik van masjinerie
ELTURIN 600 kan u laat duiselig voel, of u kan problem met u visie ervaar. Moet nie masjinerie gebruik of bestuur as u hierdie newe effekte ervaar nie.

3. HOE OM ELTURIN 600 TE NEEM

- Moet nie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.
- Die aanbevole dosis van **ELTURIN 600** is een filmbedekte tablet, geneem saam met water, tweekeer per dag (elke twaalf uur) met of sonder voedsel.
- Neem altyd u **ELTURIN 600** presies soos wat u dokter of apteker u aanbeveel het. Raadpleeg u dokter of apteker indien u twyfel.
- n Behandelingskursus duur gewoonlik 10 tot 14 dae, maar kan tot 28 dae duur. Die veiligheid en effektiwiteit van **ELTURIN 600** is nie vasgestel vir behandelingsperiodes langer as 28 dae nie.
- U dokter sal u vertel hoe lank u behandeling met **ELTURIN 600** sal duur. Moet nie die behandeling vroeg stop nie.
- As u onder die indruk is dat die effek van **ELTURIN 600** te sterk of te swak is, vertel u dokter of apteker.
- Bly onder die sorg van 'n gesondheidsorgverskaffer wanneer u **ELTURIN 600** gebruik. Moet nie u behandeling verander of stop voordat u nie eers met u gesondheidsorgverskaffer gepraat het nie.

Indien u meer ELTURIN 600 geneem het as wat u moes
Soek dadelik mediese hulp indien u vermoed dat u te veel **ELTURIN 600** geneem het.
In die geval van 'n oordosis, kontak u dokter of apteker onmiddellik. Indien nie een beskikbaar is nie, soek hulp of kontak die naaste hospitaal of vergiftigingsbeheersentrum.

Indien u vergeet om ELTURIN 600 te neem
Indien u vergeet om 'n dosis te neem, neem dit sodra u onthou, en gaan dan voort met die behandeling soos voorheen. Moet nie 'n dubbele dosis neem om vir die oorgeslane dosis op te maak nie.

Indien u stop om ELTURIN 600 te neem
Moet nie ophou om **ELTURIN 600** te neem nie, tensy u dokter u beveel om die behandeling te staak. Vra u dokter of apteker indien u enige vrae het oor die gebruik van **ELTURIN 600.**
Hoe lank u **ELTURIN 600** moet neem, sal afhang van u infeksie.
Dit is belangrik dat u die kursus voltooi, selfs al voel u na 'n paar dae beter. Indien u te gou ophou om **ELTURIN 600** te neem, sal u infeksie moontlik nie heeltemal genees word nie, en die infeksie kan terugkeer, of u toestand kan erger word. Die bakterieë wat u infeksie veroorsaak, kan weerstandig raak teen **ELTURIN 600.**
Die aanbevole dosis en die duur van die behandeling moet nie oorskry word nie.

4. Moontlike newe-effekte

ELTURIN 600 kan newe-effekte hê.
Nie alle newe-effekte wat vir **ELTURIN 600** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Indien u algemene gesondheidstoestand vererger of indien u enige ongewenste effekte ervaar terwyl u **ELTURIN 600** gebruik, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgwerker vir advies.
Indien enige van die volgende gebeur, staak die inname van **ELTURIN 600** en vertel dadelik vir u dokter of gaan na die ongevalle-afdeling by u naaste hospitaal.
- Skielike tekens van allergie – insluitend veluitslag, jeuk of netelroos; swelling van die gesig, lippe of tong, kortasem of moeilike asemhaling.

Hierdie is ernstige newe-effekte en indien u dit het, kan u 'n ernstige allergiese reaksie op **ELTURIN 600** hê. U kan dringende mediese aandag of hospitalisasie benodig.

Vertel u dokter onmiddellik of gaan na die naaste hospitaal se ongevalle-afdeling indien u enige van die volgende waarneem:
- Velreaksies soos 'n rooi, seer vel en afskilfering (dermatitis), uitslag, jeuk of swelling, veral om die gesig en nek. Dit kan die teken wees van 'n allergiese reaksie en dit kan nodig wees dat u moet ophou om **ELTURIN 600** te neem.
- Probleme met u visie, soos dowwe visie, veranderinge in kleurvisie, probleme om detail te sien of as u gesigsveld beperk word.
- Ernstige diarree wat bloed en/of slym bevat (antibiotiese geassosieerde kolitis, insluitend pseudomembraneuse kolitis), wat in minder gereelde omstandighede kan lei tot lewensgevaarlike komplikasies.
- Herhalende naarheid of braking, maagpyn of vinnige asemhaling (tekens van melksuurasidose).
- Nierversaking. Simptome van nierversaking is te wyte aan die opbou van afvalprodukte en 'n oormaat vloeistof in die liggaam wat swakheid, kortasem, lusteloosheid, swelling en verwarring kan veroorsaak.
- Inflammasie van die pankreas. Simptome sluit in pyn in die boonste deel van die maag, naarheid en braking.
- Stuipe of aanvalle.

Hierdie is ernstige newe-effekte en u kan dringende mediese aandag benodig.
Vertel ook vir u dokter indien u enige van die volgende opmerk:
Gereelde newe-effekte:
- Hoofpyn, metaalagtige smaak in die mond.
- Diarree, naarheid, braking, maagpyn, krampe of uitsetting.
- Swaminfeksie, swam/gis-infeksie in die vagina en mondholte.
- Probleme om te slaap.
- Jeuk en uitslag van die vel.
- Veranderinge in sommige bloedtoetsresultate, insluitend dié wat u nier-, lewerfunksie of bloedsuikervlakke meet.

Minder gereelde newe-effekte:
- Bloedarmoede met simptome van moegheid, hoofpyn, kortasem wanneer u oefen, duiseligheid en bleekheid.
- Gereelde infeksies soos koors, ernstige kouekoors, seerkeel of mondsere (tekens van leukopenie of neutropenie (vermindering van witbloedselle)).
- Pansitopenie ('n seldsame soort bloedarmoede waarin die rooibloedselle, witbloedselle en bloedplaatjies almal verminder).
- Trombositopenie (makliker bloeding of kneusing as normaal).
- Vermindering in beenmurgaktiwiteit.
- Verhoogde aantal witbloedselle (eosinofiele).
- Sideroblastiese anemie (bloedarmoede as gevolg van die vorming van ingeboude rooibloedselle).
- Swelling onder die veloppervlak.
- Erge allergiese reaksies.
- Hoë bloedsuiker.
- Hiponatremie (verlaagde bloednatriumvlak).
- Duiseligheid.
- Verlies van sensitiwiteit in u arms of bene of 'n gevoel van tinteling of prikkeling in u arms of bene.
- Swakheid, gevoeloosheid en pyn as gevolg van senuweeskade, gewoonlik in die hande en voete.
- Skielike, gewelddadige, onreëlmatige beweging van die liggaam.
- Probleme met visie soos dowwe visie, veranderinge in kleurvisie, probleme om detail te sien of as u gesigsveld beperk word, verlies aan visie.
- Suising in die ore (tinnitus).
- Onbehoorlike hartklop.
- Verhoogde of verlaagde bloeddruk.
- Tydelike versteuring van die bloedvloei na die brein wat korttermyn simptome veroorsaak, soos verlies aan visie, been- en armswakheid, sleeptong en verlies van bewussyn.
- Vorming van bloedklonte in die aar wat lei tot ontsteking
- Hardlywigheid, droë mond, maagpyn en ontsteking, irritasie, of erosie van die maagvoering, toename in dors, ontsteking van die mond en die tong, verkleuring van die tong, oppervlakkige tandverkleuring, los stoelgang.
- Velprobleme soos veluitslag, velontsteking, swelling van die vel en velreaksies ervaar.
- Toename in sweet.
- Haarverlies.
- Verhoging in kreatinienvlak.
- Urineer meer as normaal.
- Inflammasie van die vagina of geslagsarea by vroue.
- Kouekoors, moegheid, koors, gelokaliseerde pyn.

Minder gereelde newe-effekte wat in laboratoriumtoetse kan voorkom, is:
- Proteïene in die uriene neem toe in ensieme, verhoogde bloed ureum stikstofvlakke.
- Veranderinge in die soute (natrium, kalsium, chloried, kalium, bikarbonaat) in die bloed.
- Verhoogde of verlaagde nie-vastende glukose.
- Veranderinge in bloedseltelling, soos verhoogde retikulosiettelling (onvolwasse rooibloedselle); verlaagde neutrofiele (tipe witbloedselle).
- Veranderinge in die getalle van sekere selle of komponente in die bloed, soos witbloedselle, hemoglobien, rooibloedselle en bloedplaatjies.

Indien u enige newe-effek opmerk of ervaar wat nie in hierdie inligtingstuk aangemeld is nie, stel asseblief u dokter of apteker in kennis.

Rapportering van newe effekte
Indien u enige newe effekte waarneem of ervaar, praat asseblief met u dokter of apteker of verpleegster. Dit sluit enige moontlike newe-effekte wat nie in hierdie inligtingstuk gelys is nie, in. U kan newe effekte aanlyn rapporteer aan die Suid-Afrikaanse Reguleringsowerheid vir Gesondheidsprodukte via die "**6.04 Adverse Drug Reaction Reporting Form**", onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8.
Indien jy newe effekte rapporteer, kan jy bydrae om meer inligting oor die veiligheid van **ELTURIN 600** te verskaf.

5. Hoe om ELTURIN 600 te bewaar

Bewaar alle medisyne buite bereik van kinders.
Bewaar by of benede 30 °C. (Kamertemperatuur)
Bewaar in die oorspronklike verpakking.
Bewaar die strokie in die buitenste karton, totdat u dit benodig om te gebruik.
Beskerm teen lig en vogtigheid.
Moet nie hierdie medisyne in 'n badkamer bêre nie.
Moet nie na die vervaldatum, aangedui op die verpakking, gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in afvoerpype of rioolsisteme (bv. toilette) gooi nie.

6. Inhoud van die verpakking en ander inligting

Wat ELTURIN 600 bevat
- Die aktiewe bestanddeel is Linesolied 600 mg.
- Die ander onaktiewe bestanddele is: kolloïdale anhidriese silika, crospovidoon, gehidrogeneerde polioksiel kaster olie, magnesiumstearaat, mikrokristallyne sellulose, povidoon (K 30) en natriumstyselglikolaat. Die filmbedekking bevat hipromellose, makrogol 6 000, gesuiwerde talk en titaandioksied.

Hoe lyk ELTURIN 600 en die inhoud van die verpakking
Wit tot naaswit, ovaalvormige, bikonvekse filmbedekte tablette, diep gekeep aan beide kante.

Stulp- of strookverpakking:
Tablette word gepak in 'n stulpverpakking met harde aluminiumfoelie en PVC-film, of in 'n strookpak van Aluminium/Aluminiumfoelie gelamineer met 'n lae-digtheid poliëtileenfilm en verder verpak in 'n buitenste karton, in pakke van 10, 20, 30 of 100.
Nie alle pakke en pakgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat en vervaardiger
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Rylaan 1, Bassonia Rock, Uitbreiding 12,
Alberton, Suid Afrika

Hierdie inligtingstuk was laas hersien in
07 Augustus 2023

Registrasienommer
54/20.1.1/0235

Toegang tot die ooreenstemmende professionele inligting
Die toepaslike professionele inligting kan verkry word by https://www/macleodspharma.com/ of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169.

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Removal of English PI, change in dimension and date of revision.

1. Product: ELTURIN 600 (Linezolid Tablets 600 mg)	
2. Country: South Africa (Private Market)	**3. Packaging component: Package Insert & Patient Information Leaflet**
4. No. of Colours: 1 Colour	**5. Pantone Shade No.: Black**
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	**8. Dimensions: 335 (L) x 280 (W) mm**
9. Design / Style: Booklet Type	**10. Item code No.: PM03917002**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 34466 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No: PM03917001**
15. Revision no: 01	**16. File Name : E:\ANDA Regulatory\South Africa\LINEZOLID 600 MG\SA Private market\ELTURIN 600 Leaflet \02\PM03917002.cdr**
Approved By:	**17. Location: Baddi**

PRD	M.A. HOLDER	MEDICAL/RAD	QC	PRODN	QA
	28/11/2024				

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa (Private Market)	**PM03917001**	**16/08/22**	**01/12/22**
2) Removal of English PI, change in dimension and date of revision.	**PM03917002**		