

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:** **S4****PROPRIETARY NAME AND DOSAGE FORM****LINOACT[®] FC** Film-coated tablet**Read all of this leaflet carefully before you start taking LINOACT FC**

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

Each LINOACT FC tablet contains 600 mg linezolid.

Inactive ingredients:

Core: Cellulose (microcrystalline), lactose monohydrate, magnesium stearate, poloxamer 407, povidone K30, silica (colloidal anhydrous), sodium starch glycolate, talc.

Coating: Blue printing ink (proprietary mixture containing FD&C Blue No. 1 as colourant), Opadry white YS-1-18202-A (containing hypromellose, macrogol and titanium dioxide).

Contains sugar (25,20 mg lactose monohydrate per tablet).

WHAT LINOBACT FC IS USED FOR

The active ingredient, linezolid, is an antibiotic of the so-called oxazolidinones group. It either stops the growth of certain types of bacteria (germs) or limits the growth of other types of bacteria that cause infections.

LINOBACT FC tablets may be used for various infections.

BEFORE YOU TAKE LINOBACT FC**Do not take LINOBACT FC:**

- if you are hypersensitive (allergic) to linezolid or any of the other ingredients of LINOBACT FC (see **WHAT LINOBACT FC CONTAINS**);
- if you are treated with monoamine oxidase inhibitors (MAOIs), or within two weeks of taking such a medicine. MAOIs (such as phenelzine, selegiline, moclobemide) may be used to treat depression or Parkinson's disease.

Take special care with LINOBACT FC:

While you are taking LINOBACT FC, your doctor may perform regular blood tests to monitor changes in your blood count (see **POSSIBLE SIDE EFFECTS**).

Your doctor will monitor your eyesight if you take LINOBACT FC for more than 28 days (see **POSSIBLE SIDE EFFECTS**).

Tell your doctor:

- if you have diarrhoea. LINOBACT FC may cause serious, life-threatening diarrhoea and inflammation of your bowels (see **POSSIBLE SIDE EFFECTS**);
- if you develop recurrent nausea or vomiting, abdominal pain or rapid breathing. You may have a serious metabolic condition and need immediate medical treatment (see **POSSIBLE SIDE EFFECTS**);

- if you 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 (see **POSSIBLE SIDE EFFECTS**);
- if you have been told that you have a low blood cell count (bone marrow suppression). Your doctor may want to check you more frequently and may tell you to avoid sick people to prevent infection;
- if you experienced agitation, confusion, coma, stiff muscles, trembling, poor coordination and fits while also taking certain antidepressants (see **Taking other medicines with LINOBACT FC**);
- if you have a history of seizures (“fits”);
- if you have high blood pressure and also tell your doctor what medicines you are taking for this (see **Taking other medicines with LINOBACT FC**);
- if you have been diagnosed with an overactive thyroid gland (symptoms may be increased appetite, weight loss or sweating);
- 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 condition that causes both a loss of contact with reality and mood problems), mental confusion or other mental problems;
- if you have porphyria (a rare inherited blood disease); or
- if you have liver or kidney problems (especially if you have dialysis).

Taking LINOACT FC with food and drink

It does not matter whether you take LINOACT FC with or without a meal.

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 this medicine may react with a substance called tyramine which is naturally present in some foods and so cause an increase in your blood pressure. If you develop a throbbing headache after eating or drinking, tell your doctor or pharmacist immediately.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking LINOACT FC.

The effect of LINOACT FC in pregnant women is unknown; you should therefore not take it during pregnancy. Tell your doctor if you are pregnant, think you may be pregnant or are trying to become pregnant.

You should not breastfeed your baby while taking LINOACT FC because it could affect your baby.

Fertility:

Information is not yet available to be sure if LINOACT FC has an effect on male fertility, but the possibility cannot be excluded.

Driving and using machinery

LINOACT FC may make you feel dizzy or you may have problems with your vision (see **POSSIBLE SIDE EFFECTS**). Do not drive or use tools or machines if this happens. LINOACT FC could interfere with your ability to drive safely or handle tools or machinery safely.

Important information about some of the ingredients of LINOACT FC

Lactose

LINOACT FC contains lactose (a type of sugar derived from milk).

Patients with the rare hereditary conditions of lactose or galactose intolerance should not take LINOACT FC.

Lactose may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with LINOACT FC

Always tell your doctor or healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines).

- You must **not take** LINOACT FC tablets if you are currently taking, or have taken within the last 14 days, MAOIs (for example phenelzine, isocarboxazid, selegiline, moclobemide). These medicines may be used to treat depression or Parkinson's disease. See **Do not take LINOACT FC**.
- Your doctor may consider prescribing another medicine if you currently take/use, or have recently taken, the following medicines:
 - Decongestant cold or flu remedies containing pseudoephedrine or phenylpropanolamine.
 - Medicines used to treat sudden, severe allergic reactions such as epinephrine (adrenaline).
 - Medicines which increase your blood pressure, such as norepinephrine (noradrenaline), dopamine and dobutamine.
 - Certain antidepressants known as tricyclic antidepressants or SSRIs (selective serotonin reuptake inhibitors), for example amitriptyline, citalopram, clomipramine, dosulepin, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine and sertraline.
 - Medicines used to treat anxiety disorders, such as buspirone.

- Medicines used to treat moderate to severe pain, such as pethidine.
- Rifampicin, an antibiotic used for TB (tuberculosis).

HOW TO TAKE LINOBACT FC

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

LINOBACT FC is a type of antibiotic that will normally be given to you in hospital, by a healthcare professional.

The usual dose is:

Adults:

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

Your doctor will decide what dose you should receive.

- The usual dose for adults and adolescents (12 years and older) is one tablet (600 mg linezolid) twice daily, which is taken per mouth, with water. It does not matter if you have eaten or not.

If you are on kidney dialysis, you should be given LINOBACT FC after dialysis.

A course of treatment usually lasts 10 to 14 days, but can last up to 28 days.

Your doctor will tell you how long your treatment with LINOBACT FC will last. Do not stop treatment early, since a full course of antibiotic treatment is necessary to kill the germs that made you ill (see below under **Effects when treatment with LINOBACT FC is stopped**).

If you have the impression that the effect of LINOBACT FC is too strong or too weak, tell your doctor or pharmacist.

If you take more LINOBACT FC than you should

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

Usually you will be in hospital while receiving LINOACT FC. Tell your healthcare professional at once if you think you may have been given too much LINOACT FC.

If you forget to take/missed a dose of LINOACT FC

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

If you think you have missed a dose, please ask your doctor or healthcare professional.

Effects when treatment with LINOACT FC is stopped

To completely clear your infection, you should take the full course of LINOACT FC, as prescribed by your doctor.

Your symptoms may improve before the infection is completely treated. Stopping early may have the effect that the germs causing the infection become resistant to LINOACT FC.

POSSIBLE SIDE EFFECTS

LINOACT FC can have side effects.

Not all side effects reported for LINOACT FC are included in this leaflet.

Should your general health worsen, or if you experience any untoward effects while taking LINOACT FC, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking LINOACT FC and tell your doctor immediately:

- Serious allergic reactions, including a shock reaction. You may have swelling of the tongue and/or throat, difficulty in swallowing, difficulties in breathing, facial swelling, severe dizziness with very fast heartbeat and heavy sweating.
- Skin reactions such as hives (nettle rash), red sore skin and flaking (dermatitis), rash, itching, or swelling, particularly around the face and neck. These signs may be

due to a severe allergic reaction and it may be necessary for you to stop taking LINOBACT FC.

- Recurrent nausea or vomiting, abdominal pain or over breathing. You may have developed lactic acidosis. This condition occurs when lactic acid builds up in the bloodstream faster than it can be removed and can be life-threatening.
- Severe diarrhoea containing blood and/or mucous (antibiotic associated colitis including pseudomembranous colitis), which can develop into complications that are life-threatening. In this situation, you should not take medicines that stop or slow bowel movement (such as loperamide).
- Unusual tiredness or weakness, which may be due to decrease in red blood cells, or their haemoglobin (iron-containing pigment) content may be too low.
- Decrease in certain white blood cells, which may affect your ability to fight infection.
- Unexplained bleeding or bruising that may be due to decrease in blood platelets.
- Fits or seizures (see **Special care should be taken with LINOBACT FC**).
- Fast heart rate, confusion, abnormal sweating, hallucinations, involuntary movements, chills and shivering. You may have developed serotonin syndrome. This happens when you have an excessive accumulation of serotonin in your body, which may occur when two medicines that affect the body's level of serotonin are taken together at the same time. See **Taking other medicines with LINOBACT FC**.
- Blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.
- Loss of vision with leg and arm weakness, slurring of speech and loss of consciousness. You may have a “mini-stroke” due to temporary disturbance of blood flow to the brain.

These are all very serious side effects. You may require urgent medical attention or further hospitalisation.

Tell your doctor if you notice any of the following:***Side effects occurring frequently:***

- Fungal infections, especially vaginal or oral “thrush”
- Difficulty in sleeping
- Headache
- Metallic taste in the mouth
- Diarrhoea, nausea (feeling sick), vomiting (being sick), abdominal pain or cramps.

Side effects occurring less frequently

- Inflammation of the vagina or genital area in women
- Dizziness, sensations such as tingling or numbness of fingers and toes
- Convulsions (“fits”)
- Blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted
- “Ringing” in the ears (tinnitus)
- Changes in heart rate (e.g., increased rate)
- Increased or decreased blood pressure (your doctor will test your blood pressure)
- Indigestion, stomach pain, constipation, thirst, loose stools
- Dry or sore mouth, swollen, sore, or discoloured tongue
- Hair loss, sweating, itching
- Superficial tooth discolouration, removable with professional dental cleaning (manual descaling)
- Excessive production of urine or small volumes of urine with swelling of the limbs and back pain (kidney problems)

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

STORAGE AND DISPOSING OF LINOBACT FC

Store all medicines out of reach of children.

Store at or below 30 °C in the original packaging. Keep bottle or blister strips in cartons until required for use. Keep bottles well-closed.

Do not store in a bathroom.

Do not take after the expiry date stated on the label and carton.

Return all unused or expired medicine to your pharmacist for safe disposal.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF LINOBACT FC

- Cardboard box containing PA/ALL/PVC - Aluminium foil (silver) blisters strips with 10 or 30 film-coated tablets.
- Cardboard box containing PVC/PE/PVDC (white) - Aluminium foil (silver) blisters with 10 or 30 film-coated tablets.
- Cardboard box containing one white opaque HDPE container (bottle) with white polypropylene child resistant screw cap and white polyethylene mounted desiccant containing silica gel, with 10 or 30 film-coated tablets and an instruction leaflet.

All pack sizes may not necessarily be marketed at one time.

IDENTIFICATION OF LINOBACT FC

LINOBACT FC tablets are white, oval, biconvex, film-coated tablets, with “600” printed on one side with blue ink.

REGISTRATION NUMBER

49/20.1.1/0721

NAME AND ADDRESS OF THE REGISTRATION HOLDER

Astral Pharma (Pty) Ltd

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Linobact FC
Each film coated tablet contains 600 mg Linezolid

125 Meade Street

George

6529

South Africa

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MANNER OF GAINING ACCESS TO PROFESSIONAL INFORMATION

To be determined