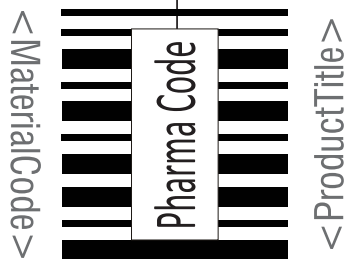


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Package Leaflet: Information for the user Linezolid 600mg Film-Coated Tablets Linezolid Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. - Keep this leaflet. You may need to read it again. - If you have any further questions, ask your doctor, or pharmacist or nurse. - This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours. - If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. What is in this leaflet 1. What Linezolid is and what it is used for 2. What you need to know before you take Linezolid 3. How to take Linezolid 4. Possible side effects 5. How to store Linezolid 6. Contents of the pack and other information 1. What Linezolid is and what it is used for Linezolid is an antibiotic of the oxazolidinones group that works by stopping the growth of certain bacteria (germs) that cause infections. It is used in adults to treat pneumonia and some infections in the skin or under the skin. Your doctor will have decided if Linezolid is suitable to treat your infection. 2. What you need to know before you take Linezolid Do not take Linezolid: • if you are allergic (hypersensitive) to linezolid or any of the other ingredients of this medicine (listed in section 6) • if you are taking or have taken within the last 2 weeks any medicines known as monoamine oxidase inhibitors (MAOIs for example phenelzine, isocarboxazid, selegiline, moclobemide). These medications may be used to treat depression or Parkinson's disease. • if you are breast-feeding. This is because linezolid passes into breast milk and could affect the baby. Warning and precautions Linezolid may not be suitable for you if you answer yes to any of the following questions. In this case tell your doctor as he/she will need to check your general health and your blood pressure before and during your treatment, or may decide that another treatment is better for you. Ask your doctor if you are not sure whether these categories apply to you. • Do you have high blood pressure? • Have you been diagnosed with an overactive thyroid? • Do 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)? • Do you suffer from manic depression, schizoaffective disorder, mental confusion or other mental problems? • Are you taking any of the following medicines? - decongestant cold or flu remedies containing pseudoephedrine or phenylpropanolamine - medicines used to treat asthma such as salbutamol, terbutaline, fenoterol - antidepressants known as tricyclics or SSRIs (selective serotonin reuptake inhibitors) for example amitriptyline, cipramil, clomipramine, dosulepin, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine; sertraline - medicines used to treat migraine such as 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 moderate to severe pain, such as pethidine - medicines used to treat anxiety disorders, such as buspirone - an antibiotic called rifampicin. Take special care with Linezolid Talk to you doctor, pharmacist or nurse before taking Linezolid if you • bruise and bleed easily • are anaemic (have low red blood cells) • are prone to getting infections • have a history of seizures • have liver problems or kidney problems particularly if you have dialysis • have diarrhoea Tell your doctor immediately if during treatment you suffer from • problems with your vision such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted. • loss of sensitivity in your arms or legs or a sensation of tingling or pricking in your arms or legs. • You may develop diarrhoea while taking or after taking antibiotics, including Linezolid. If this becomes severe or persistent or you notice that your stool contains blood or mucus, you should stop taking Linezolid immediately and consult your doctor. In this situation, you should not take medicines that stop or slow bowel movement. • recurrent nausea or vomiting, abdominal pain or over breathing Other medicines and Linezolid There is a risk that Linezolid may sometimes interact with certain other medicines to cause side effects such as changes in blood pressure, temperature or heart rate Tell your doctor if you are taking or have taken within the last 2 weeks the following medicines as Linezolid must not be taken if you are already taking these medicines or have taken them recently. (See also Section 2 above ‘Do not take Linezolid’. • monoamine oxidase inhibitors (MAOIs for example phenelzine, isocarboxazid, selegiline, moclobemide). These may be used to treat depression or Parkinson's disease Also tell your doctor if you are taking the following medicines. Your doctor may still decide to give you Linezolid, but will need to check your general health and your blood pressure before and during your treatment. In other cases, your doctor may decide that another treatment is better for you. • Decongestant cold or flu remedies containing pseudoephedrine or phenylpropanolamine. • Some medicines used to treat asthma such as salbutamol, terbutaline, fenoterol. • Certain antidepressants known as tricyclics or SSRIs (selective serotonin reuptake inhibitors). There are many of these, including amitriptyline, cipramil, clomipramine, dosulepin, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine, sertraline. • Medicines used to treat migraine such as 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 moderate to severe pain, such as pethidine. • Medicines used to treat anxiety disorders, such as buspirone. • Medicines that stop blood clotting, such as warfarin. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Linezolid with food and drink • You can take Linezolid either before, during or after 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. This interaction may cause an increase in your blood pressure. • If you develop a throbbing headache after eating or drinking, tell your doctor or pharmacist immediately. Pregnancy, breast-feeding and fertility The effect of Linezolid in pregnant women is not known. Therefore it should not be taken in pregnancy unless advised by your doctor. Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should not breastfeed when taking Linezolid because it passes into breast milk and could affect the baby. Driving and using machines Linezolid 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. Linezolid contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. 3. How to take Linezolid Adults Always take this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure. The usual dose is one tablet (600 mg linezolid) twice daily (every twelve hours). Swallow the tablet whole with some water. If you are on kidney dialysis, you should take Linezolid after dialysis treatment. A course of treatment usually lasts 10 to 14 days but can last up to 28 days. The safety and effectiveness of this medicine have not been established for treatment periods longer than 28 days. Your doctor will decide how long you should be treated. While you are taking Linezolid, your doctor should perform regular blood tests to monitor your blood count. Your doctor should monitor your eyesight if you take Linezolid for more than 28 days. Use in children Linezolid is not normally used to treat children and adolescents (under 18 years old). If you take more Linezolid than you should Tell your doctor or pharmacist immediately.		



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