



<p>Page 2 Reverse of Top Panel</p> <p>PATIENT INFORMATION LEAFLET Erythromycin ethyl succinate 125 mg/5 ml Granules for Oral Suspension Erythromycin ethyl succinate</p> <p>Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.</p> <p>Keep this leaflet. You may need to read it again.</p> <p>If you have any further questions, ask your doctor or pharmacist.</p> <p>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.</p> <p>If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.</p> <p>What is in this leaflet:</p> <ol style="list-style-type: none"> What Erythromycin is and what it is used for What you need to know before you take Erythromycin How to take Erythromycin Possible side effects How to store Erythromycin Contents of the pack and other information <p>70. mm</p>	<p>Page 3</p> <p>1. WHAT ERYTHROMYCIN IS AND WHAT IT IS USED FOR Erythromycin contains erythromycin ethyl succinate, which is an antibiotic (macrolide group). It is used to treat or prevent bacterial infections, including sexually transmitted diseases and dental infections. It may be used to prevent whooping cough, diphtheria or to treat certain skin infections (<i>Acne vulgaris</i>).</p> <p>2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ERYTHROMYCIN Do not take Erythromycin:</p> <ul style="list-style-type: none"> if you are allergic to erythromycin or any of the other ingredients of this medicine (listed in section 6) if you are currently taking a medicine called - ergotamine or dihydroergotamine (used to treat migraines) as this may cause serious side effects while taking erythromycin terfenadine or astemizole or mizolastine (widely taken for hayfever and allergies), domperidone (for nausea (feeling sick) and vomiting (being sick)), cisapride (for stomach disorders) or pimozide or amisulpride (for psychiatric conditions) while receiving erythromycin, as combining these drugs can sometimes cause serious disturbances in heart rhythm. Consult your doctor for advice on alternative medicine you can take instead <p>68.5 mm</p>	<p>Page 4</p> <ul style="list-style-type: none"> simvastatin (used to lower cholesterol and triglycerides (types of fat in the blood)) tolterodine (used for treating overactive bladder with symptoms of urinary frequency, urgency and leakage) lorazepam (used to lower increased blood fats such as cholesterol and triglycerides). Taking this medicine at the same time as erythromycin may lead to a rise in enzymes produced by liver cells (transaminases), which indicates that the liver is under stress and may lead to liver problems if you have abnormally low levels of potassium or magnesium in your blood (hypokalaemia or hypomagnesaemia) if you or someone in your family has a history of heart rhythm disorders (ventricular cardiac arrhythmia or torsades de pointes) or an abnormality of the electrocardiogram (electrical recording of the heart called "long QT syndrome"). <p>Warnings and precautions Talk to your doctor or pharmacist before taking Erythromycin:</p> <ul style="list-style-type: none"> if you are taking cochlchine (used for treatment of gout and arthritis) as this may cause serious side effects whilst taking erythromycin if you have any liver problems or have been told that any drugs you are taking can cause liver problems <p>67.5 mm</p>	<p>Page 5</p> <ul style="list-style-type: none"> if you have previously experienced diarrhoea following the use of antibiotics if you are pregnant and have been told that you have a sexually transmitted disease called syphilis. In this case erythromycin may not be effective for preventing the transfer of this infection to your baby. Alternatively if you were treated for early stages of syphilis during your pregnancy, and your child is under 1 year and is prescribed erythromycin, consult your doctor before giving erythromycin to your child if you are treating a young child with antibiotics and they are irritable or vomit when fed if you suffer from a condition called myasthenia gravis, which causes muscle weakness if you are taking erythromycin with 'statins' such as simvastatin or lovastatin (used to lower cholesterol) if you are taking other medicines which are known to cause serious disturbances in heart rhythm if you have heart problems. <p>Contact your doctor as soon as possible if you develop watery and bloody stools during or up to 2 months after treatment, with or without stomach cramps and fever (to rule out the possibility of pseudomembranous colitis).</p> <p>66. mm</p>	<p>Page 6</p> <p>Other medicines and Erythromycin Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important if you are taking medicines from the following families:</p> <ul style="list-style-type: none"> antienziolate, terfenadine or mizolastine (used to treat allergies such as hay fever) domperidone (used to treat nausea and vomiting) pimozide (used to treat mental problems) ergotamine or dihydroergotamine (for migraines) cisapride (for stomach disorders) statins (used to help lower cholesterol levels e.g. lovastatin and simvastatin) protease inhibitors (used to treat viral infections e.g. saquinavir) oral contraceptives. <p>This is also important if you are taking medicines called:</p> <ul style="list-style-type: none"> cochlchine (used to treat gout and arthritis) cimetidine and omeprazole (used to treat acid reflux and other related conditions) clarithromycin, rifabutin, or rifampicin (medicines used to <p>66. mm</p>	<p>Page 7</p> <p>treat different types of bacterial infections)</p> <ul style="list-style-type: none"> fluconazole, ketconazole and itraconazole (medicines used to treat fungal infections) digoxin, quinidine or disopyramide (used to treat heart problems) clotazolol (a medicine used to treat peripheral circulation problems) hexobarbitone, phenobarbital or midazolam (used as sedatives) antipsychotics e.g. warfarin, aceonocoumarol and rivaroxaban (used to thin the blood) valproate, carbamazepine or phenytoin (used to control epilepsy) theophylline (used to treat asthma and other breathing problems) zopiclone or triazolam/alprazolam (used to help you sleep or relieve states of anxiety) alfentanil (a medicine used to provide pain relief) methylprednisolone (used to help suppress the body's immune system – this is useful in treating a wide range of <p>67.5 mm</p>	<p>Page 8</p> <p>conditions)</p> <ul style="list-style-type: none"> St John's Wort (a herbal medicine used to treat depression) verapamil (used to treat high blood pressure and chest pain) vinflaxine (used to treat certain types of cancer) sildenafil (used to treat erectile dysfunction) corticosteroids, given by mouth, by injection or inhaled (used to help suppress the body's immune system – this is useful in treating a wide range of conditions) hydroxychloroquine or chloroquine (used to treat conditions including rheumatoid arthritis, or to treat or prevent malaria). Taking these medicines at the same time as erythromycin may increase the chance of getting abnormal heart rhythm and other serious side effects that affect your heart. <p>If you or your child goes for any medical tests, tell your doctor that you are taking Erythromycin, as this may interfere with some test results.</p> <p>Pregnancy and breast-feeding If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. The active ingredient of Erythromycin may cross the placenta</p> <p>68.5 mm</p>	<p>Page 9</p> <p>in pregnant women and is excreted in breast milk. Information from studies regarding the risk of birth defects is inconclusive, but some studies have reported heart defects following Erythromycin use in early pregnancy. Erythromycin should be used by women during pregnancy or while breast-feeding only if clearly needed.</p> <p>Erythromycin contains sucrose and sodium If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This medicine contains 46.53 mg/5 ml of sodium. To be taken into consideration by patients on a controlled sodium diet.</p> <p>3. HOW TO TAKE ERYTHROMYCIN Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Patients with kidney problems must be given a reduced dose. Shake Erythromycin well before use. Taking Erythromycin with food and drink: Take Erythromycin before meals.</p> <p>67.5 mm</p>
<p>Page 10</p> <p>The recommended doses are:</p> <p>For adults and children over 8 years of age: 2 g per day in divided doses. In severe infections, this can increase up to 4 g per day in divided doses. Two to four 5 ml spoonfuls four times a day.</p> <p>For <i>Acne vulgaris</i>: the dose is two 5 ml spoonfuls 3 times daily before meals, for 1 to 4 weeks, and then reduced to twice daily until improvement occurs.</p> <p>For children aged 2 - 8 years: 30 mg per kg of bodyweight per day in divided doses. In severe infections, this can increase up to 50 mg per kg of bodyweight per day in divided doses. Two to 5 ml spoonfuls four times a day or as advised by your doctor.</p> <p>For infants under 2 years of age: 30 mg per kg of bodyweight per day in divided doses. In severe infections, this can increase up to 50 mg per kg of bodyweight per day in divided doses. One 5 ml spoonful four times a day or as advised by your doctor. An oral syringe may be used to measure this dose.</p> <p>If you forget to take Erythromycin Take the dose as soon as you remember, unless it is nearly time</p> <p>67.5 mm</p>	<p>Page 11</p> <p>for your next dose. Do not take a double dose to make up for the missed dose.</p> <p>If you take more Erythromycin than you should If you accidentally take more medicine in one day than your doctor has told you to, or if a child has taken some of the medicine by mistake, contact your doctor or go to your nearest hospital emergency department immediately. An overdose could cause temporary hearing loss, nausea, vomiting and diarrhoea.</p> <p>If you stop taking Erythromycin Continue to take this medicine until the course is completed or until your doctor tells you to stop; do not stop taking your medicine, even if you feel better. If you stop the treatment too early your problem could come back.</p> <p>If you have any further questions on the use of this medicine, ask your doctor or pharmacist.</p> <p>4. POSSIBLE SIDE EFFECTS Like all medicines, this medicine can cause side effects, although not everybody gets them. Contact a doctor immediately if you experience a serious skin reaction: a red, scaly rash with bumps under the skin and blisters</p> <p>68.5 mm</p>	<p>Page 12</p> <p>(exanthematous pustulosis). The frequency of this side effect is not known (cannot be estimated from the available data).</p> <p>If you notice any of the following, contact your doctor immediately: difficulty breathing, fainting, swelling of the face, lips or throat, skin rashes, severe skin reactions including large fluid-filled blisters, sores and ulcers, ulcers in the mouth or throat. These may be signs of an allergic reaction.</p> <p>Other side effects of Erythromycin include:</p> <ul style="list-style-type: none"> diarrhoea which may be severe or prolonged and may contain blood or mucus feeling of being sick increase in a particular type of white blood cells (eosinophils) stomach pains; these may be a symptom of an inflamed pancreas (pancreatitis) ringing in the ears (tinnitus) reversible loss of hearing (usually associated with high doses or in patients with kidney problems) various liver or gall bladder problems, which can cause yellowing of the skin and/or eyes (jaundice) or pale stools with dark urine chest pain <p>67.5 mm</p>	<p>Page 13</p> <ul style="list-style-type: none"> abnormal heart rhythms (including palpitations, a faster heartbeat, a life-threatening irregular heart beat called torsades de pointes or abnormal ECG heart tracing) or heart stopping (cardiac arrest) fever loss of appetite confusion fits (seizures) vertigo (problems with balance that can result in feelings of dizziness or sickness – particularly on standing) hallucinations (seeing or hearing things that aren't there) feeling generally unwell (malaise) inflammation of the kidneys (a condition known as interstitial nephritis) low blood pressure serious skin rashes that may involve blistering and can cover large areas of the torso, face and limbs (conditions known as Stevens Johnson syndrome, toxic epidermal necrolysis and erythema multiforme) vomiting and irritability in young children between the age of 1 and 12 months visual impairment/blurred vision (Mitochondrial optic neuropathy). <p>Reporting of side effects If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.</p> <p>5. HOW TO STORE ERYTHROMYCIN Keep this medicine out of the sight and reach of children. Do not use your medicine after the expiry date which is stated on the label. Once the granules are reconstituted by your doctor or pharmacist, store below 25 °C. Keep the cap tightly closed, and use within 14 days. Do not freeze. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.</p> <p>66. mm</p>	<p>Page 14</p> <p>neuropathy).</p> <p>6. CONTENTS OF THE PACK AND OTHER INFORMATION What Erythromycin contains</p> <ul style="list-style-type: none"> the active substance is erythromycin ethyl succinate; each 5 ml of the oral suspension contains erythromycin 125 mg, the other ingredients are sodium carboxymethylcellulose, sodium citrate, banana flavour (E4210), quinoline yellow (E104), sodium saccharin, colloidal silicon dioxide and sucrose (see end of Section 2). <p>What Erythromycin looks like and contents of the pack Erythromycin comes as granules for preparation by your pharmacist. Once reconstituted it is a yellow liquid. It is available in 100 ml amber glass with pilfer evident caps or white plastic HDPE bottles with pilfer proof screw caps or child resistant caps, and is also available in strengths of 250 mg or 500 mg per 5 ml.</p> <p>Marketing Authorisation Holder and Manufacturer Pinewood Laboratories Ltd., Ballymacarthy, Clonsilla, Co. Tipperary, Ireland. PL 049170013 This leaflet was last updated in 02/2023</p> <p>67.5 mm</p>	<p>Page 15</p> <p>6. CONTENTS OF THE PACK AND OTHER INFORMATION What Erythromycin contains</p> <ul style="list-style-type: none"> the active substance is erythromycin ethyl succinate; each 5 ml of the oral suspension contains erythromycin 125 mg, the other ingredients are sodium carboxymethylcellulose, sodium citrate, banana flavour (E4210), quinoline yellow (E104), sodium saccharin, colloidal silicon dioxide and sucrose (see end of Section 2). <p>What Erythromycin looks like and contents of the pack Erythromycin comes as granules for preparation by your pharmacist. Once reconstituted it is a yellow liquid. 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To reconstitute, first shake bottle to loosen powder, then add 60 ml water and shake the bottle vigorously until granules are fully suspended. The resulting 100 ml of suspension contains 125 mg of Erythromycin activity in each 5 ml. Pinewood Laboratories Ltd., [PDL] Ireland. PL 049170013 28.02.2023</p> <p>67.5 mm</p>	

Braille Translation:

ERYTHROMYCIN ETHYL SUCCINATE
#125 MG/ #5 ML