



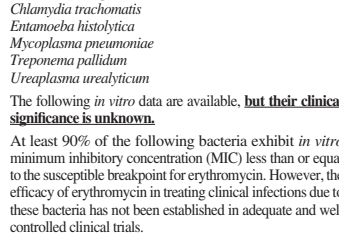
(Nos. 6346) XX-XXXX-R1-Rev. July, 2013 ERYTHROCIN® STEARATE ERYTHROMYCIN STEARATE TABLETS, USP Film-coated Tablets Only

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To reduce the development of drug-resistant bacteria and maintain the effectiveness of ERYTHROCIN® STEARATE Film-coated tablets and other antibacterial drugs, ERYTHROCIN® STEARATE Film-coated tablets should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

DESCRIPTION
ERYTHROCIN® STEARATE Film-coated tablets (erythromycin stearate tablets, USP) are an antibacterial product containing the stearate salt of erythromycin in a unique film coating.

Erythromycin is produced by a strain of *Saccharophytomyces erythraeus* (formerly *Streptomyces erythraeus*) and belongs to the macrolide group of antibiotics. It is basic and readily forms salts with acids. Erythromycin is a white to off-white powder, slightly soluble in water, and soluble in alcohol, chloroform, and ether. Erythromycin stearate is known chemically as erythromycin octadecanoate. The molecular formula of erythromycin stearate is C₄₄H₇₆N₂O₁₃ · C₁₈H₃₄O₂ and the molecular weight is 1018.43. The structural formula is:



Inactive Ingredients:
250 mg tablet: Cellulosic polymers, corn starch, D&C Red No. 7, polyacrylin potassium, polyethylene glycol, povidone, propylene glycol, sodium calcium methylcellulose, sodium citrate, sorbic acid, sorbitan monooleate and titanium dioxide.

CLINICAL PHARMACOLOGY
Orally administered erythromycin base and its salts are readily absorbed in the microbologically active form. Interindividual variations in the absorption of erythromycin are, however, observed, and some patients do not achieve optimal serum levels. Erythromycin is largely bound to plasma proteins. After absorption, erythromycin diffuses readily into most body fluids. In the absence of meningeal inflammation, low concentrations are normally achieved in the spinal fluid but the passage of erythromycin across the blood-tissue barrier increases in meningitis. Erythromycin crosses the placental barrier, but fetal plasma levels are low. The drug is excreted in human milk. Erythromycin is not removed by peritoneal dialysis or hemodialysis.

In the presence of normal hepatic function, erythromycin is concentrated in the liver and is excreted in the bile; the effect of hepatic dysfunction on biliary excretion of erythromycin is not known. After oral administration, less than 5% of the administered dose can be recovered in the active form in the urine.

Orally administered ERYTHROCIN® STEARATE tablets are readily and reliably absorbed. Optimal serum levels of erythromycin are reached when the drug is taken in the fasted state or immediately before meals.

Microbiology
Mechanism of Action
Erythromycin acts by inhibition of protein synthesis by binding 50S ribosomal subunits of susceptible organisms. It does not affect nucleic acid synthesis.

Mechanism of Resistance
The major route of resistance is modification of the 23S rRNA in the 50S ribosomal subunit to insensitivity while efflux can also be significant.

Interactions with Other Antibiotics
Antagonism exists *in vitro* between erythromycin and clindamycin, lincomycin, and chloramphenicol.

Erythromycin has been shown to be active against most isolates of the following bacteria both *in vitro* and in clinical infections as described in the INDICATIONS AND USAGE section.

Gram-positive Bacteria:
Corynebacterium diphtheriae
Corynebacterium minutissimum
Listeria monocytogenes
Saphylococcus aureus (resistant organisms may emerge during treatment)
Streptococcus pneumoniae
Streptococcus pyogenes

Gram-negative Bacteria:
Bordetella pertussis
Haemophilus influenzae
Legionella pneumophila
Neisseria gonorrhoeae

Other Microorganisms:
Chlamydia trachomatis
Entamoeba histolytica
Mycoplasma pneumoniae
Treponema pallidum
Ureaplasma urealyticum

The following *in vitro* data are available, but their clinical significance is unknown.

At least 90% of the following bacteria exhibit *in vitro* minimum inhibitory concentration (MIC) less than or equal to the susceptible breakpoint for erythromycin. However, the efficacy of erythromycin in treating clinical infections due to these bacteria has not been established in adequate and well controlled clinical trials.

Gram-positive Bacteria:
Viridans group streptococci

Gram-negative Bacteria:
Moraxella catarrhalis

Susceptibility Test Methods
When available the clinical microbiology laboratory should provide the results of *in vitro* susceptibility test results for antimicrobial drug products used in resident hospitals to the physician as periodic reports that describe the susceptibility profile of nosocomial and community-acquired pathogens. These reports should aid the physician in selecting the antibacterial drug product for treatment.

Quantitative methods are used to determine antimicrobial minimum inhibitory concentrations (MIC's). These MICs provide estimates of the susceptibility of bacteria to antimicrobial compounds. The MICs should be determined using a standardized test method.^{1,2} This procedure uses paper disks impregnated with 15 mcg erythromycin to test the susceptibility of microorganisms to erythromycin. The disc diffusion interpretive criteria are provided in Table 1.

Diffusion techniques:
Quantitative methods that require measurement of zone diameters can also provide reproducible estimates of the susceptibility of bacteria to antimicrobial compounds. The zone size provides an estimate of the susceptibility of bacteria to antimicrobial compounds. The zone size should be determined using a standardized test method.^{1,2} This procedure uses paper disks impregnated with 15 mcg erythromycin to test the susceptibility of microorganisms to erythromycin. The disc diffusion interpretive criteria are provided in Table 1.

Table 1. In Vitro Susceptibility Test Interpretive Criteria for Erythromycin

Pathogen	Minimum Inhibitory Concentrations (zone diameters in mm)				Disk Diffusion (zone diameters in mm)				
	S	I	R	S	I	R	S	I	R
<i>Staphylococcus aureus</i>	≤0.5	1-4	≥8	≥23	14-22	≥13			
<i>Streptococcus pneumoniae</i>	≤0.25	0.5	≥1	≥21	16-20	≥15			
<i>Streptococcus pyogenes</i>	≤0.25	0.5	≥1	≥21	16-20	≥15			

A report of "Susceptible" indicates that the antimicrobial is likely to inhibit growth of the pathogen if the antimicrobial compound reaches the concentrations at the site of infection necessary to inhibit growth of the pathogen. A report of "Intermediate" indicates that the result should be considered equivocal, and if the microorganism is not fully susceptible to alternative, clinically feasible drugs, the test should be repeated. This category implies possible clinical applicability in body sites where the drug product is physiologically concentrated or in situations where high dosage of drug can be used. This category also includes a buffer zone which prevents small uncontrolled technical factors from causing major discrepancies in interpretation. A report of "Resistant" indicates that the antimicrobial is not likely to inhibit growth of the pathogen if the antimicrobial compound reaches the concentrations usually achievable at the infection site; other therapy should be selected.

Quality Control:
Standardized susceptibility test procedures require the use of laboratory controls to monitor and ensure the accuracy and precision of controls and reagents used in the assay, and the techniques of the individuals performing the test.^{1,2} Standard erythromycin powder should provide the following range of MIC values noted in Table 2. For the diffusion technique using the 15 mcg disk, the criteria in Table 2 should be achieved.

Table 2. Acceptable Quality Control Ranges for Erythromycin

QC Strain	Minimum Inhibitory Concentrations (mcg/mL)	Disk Diffusion (zone diameters in mm)
<i>Staphylococcus aureus</i> ATCC 29213	0.25-1	NA
<i>Staphylococcus aureus</i> ATCC 25923	NA	22-30
<i>Enterococcus faecalis</i> ATCC 29212	1-4	NA
<i>Streptococcus pneumoniae</i> ATCC 49619	0.03-0.12	25-30

INDICATIONS AND USAGE

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ERYTHROCIN® STEARATE tablets are indicated in the treatment of infections caused by susceptible strains of the designated microorganisms in the diseases listed below.

Upper respiratory tract infections of mild to moderate degree caused by *Streptococcus pneumoniae*, *Streptococcus pneumoniae*, *Haemophilus influenzae* (when used concomitantly with adequate doses of sulfonamides, since many strains of *H. influenzae* are not susceptible to the erythromycin concentrations ordinarily achieved). (See appropriate sulfonamide labeling for prescribing information.)

Lower respiratory tract infections of mild to moderate severity caused by *Streptococcus pyogenes* or *Streptococcus pneumoniae*.

Listeriosis caused by *Listeria monocytogenes*.

Respiratory tract infections due to *Mycoplasma pneumoniae*.

Skin and skin structure infections of mild to moderate severity caused by *Streptococcus pyogenes* or *Staphylococcus aureus* (resistant *Staphylococci* may emerge during treatment).

Pertussis (whooping cough) caused by *Bordetella pertussis*. Erythromycin is effective in eliminating the organism from the nasopharynx of infected individuals, rendering them noninfectious. Some clinical studies suggest that erythromycin may be helpful in the prophylaxis of pertussis in exposed susceptible individuals.

Diphtheria. Erythromycin due to *Corynebacterium diphtheriae*, as an adjunct to antitoxin to prevent establishment of carriers and to eradicate the organism in carriers.

Erythrasma: In the treatment of erythrasma by *Corynebacterium minutissimum*.

Intestinal amebiasis caused by *Entamoeba histolytica* (oral erythromycin only). Extraintestinal amebiasis requires treatment with other agents.

Acute pelvic inflammatory disease caused by *Neisseria gonorrhoeae*: Erythrocin[®] Lactobionate-LV, (erythromycin lactobionate for injection, USP) followed by erythromycin base orally, as an alternative drug in treatment of acute pelvic inflammatory disease caused by *N. gonorrhoeae* in female patients with a history of sensitivity to penicillin. Patients should have a serologic test for syphilis before receiving erythromycin as treatment of gonorrhea and a follow-up serologic test for syphilis after 3 months.

Erythromycins are indicated for treatment of the following infections caused by *Chlamydia trachomatis*: conjunctivitis of the newborn, pneumonia of infancy, and urogenital infections during pregnancy. When tetracyclines are contraindicated or not tolerated, erythromycin is indicated for the treatment of uncomplicated urethral, endocervical, or rectal infections in adults due to *Chlamydia trachomatis*.

When tetracyclines are contraindicated or not tolerated, erythromycin is indicated for the treatment of nongonococcal urethritis caused by *Ureaplasma urealyticum*.

Primary syphilis caused by *Treponema pallidum*. Erythromycin (oral form only) is an alternative choice of treatment for primary syphilis in patients allergic to the penicillins. In treatment of primary syphilis, spinal fluid should be examined before treatment and as part of the follow-up after therapy.

Legionnaires' Disease: caused by *Legionella pneumophila*. Although no controlled clinical efficacy studies have been conducted, *in vitro* and limited preliminary clinical data suggest that erythromycin may be effective in treating Legionnaires' Disease.

PRECAUTIONS

Contraindications
Erythromycin is contraindicated in patients with known hypersensitivity to this antibiotic.

Erythromycin is contraindicated in patients taking terfenadine, astemizole, cisapride, pimozide, ergotamine, or dihydroergotamine. (See **PRECAUTIONS - Drug Interactions**.)

WARNINGS
Hepatotoxicity
There have been reports of hepatic dysfunction, including increased liver enzymes, and hepatocellular and/or cholestatic hepatitis, with or without jaundice, occurring in patients receiving oral erythromycin products.

QT Prolongation
QT prolongation has been associated with prolongation of the QT interval and infrequent cases of arrhythmia. Cases of torsades de pointes have been spontaneously reported during postmarketing surveillance in patients receiving erythromycin. Facilities have been reported. Erythromycin should be avoided in patients with known prolongation of the QT interval, patients with ongoing proarrhythmic conditions such as uncorrected hypokalemia or hypomagnesemia, clinically significant bradycardia, and in patients receiving Class IA (quinidine, procainamide) or Class III (dofetilide, amiodarone, sotalolol) antiarrhythmic agents. Elderly patients may be more susceptible to drug-associated effects on the QT interval.

Syphilis in Pregnancy
There have been reports suggesting that erythromycin does not reach the fetus in adequate concentration to prevent congenital syphilis. Infants born to women treated during pregnancy with oral erythromycin for early syphilis should be treated with an appropriate penicillin regimen.

Clostridium difficile Associated Diarrhea (CDAD)
Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including ERYTHROCIN® STEARATE Film-coated tablets, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

Drug Interactions
Serious adverse reactions have been reported in patients taking erythromycin concomitantly with CYP3A4 substrates. These include colchicine toxicity with colchicine; rhabdomyolysis with simvastatin, lovastatin, and atorvastatin; and hypokalemia with calcium channel blockers metabolized by CYP3A4 (e.g., verapamil, nifedipine, diltiazem) (see **PRECAUTIONS - Drug Interactions**).

There have been post-marketing reports of colchicine toxicity with concomitant use of erythromycin and colchicine. This interaction is potentially life-threatening, and may occur while using both drugs at their recommended doses (see **PRECAUTIONS - Drug Interactions**).

Rhabdomyolysis with or without renal impairment has been reported in seriously ill patients receiving erythromycin concomitantly with lovastatin. Therefore, patients receiving concomitant lovastatin and erythromycin should be carefully monitored for creatine kinase (CK) and serum transaminase levels. (See package insert for lovastatin.)

PRECAUTIONS

General
Prescribing ERYTHROCIN® STEARATE Film-coated tablets in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Since erythromycin is principally excreted by the liver, caution should be exercised when erythromycin is administered to patients with impaired hepatic function. (See **CLINICAL PHARMACOLOGY AND WARNINGS**.)

CLINICAL PHARMACOLOGY AND WARNINGS
Exacerbation of symptoms of myasthenia gravis and new onset of symptoms of myasthenic syndrome has been reported in patients receiving erythromycin therapy.

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