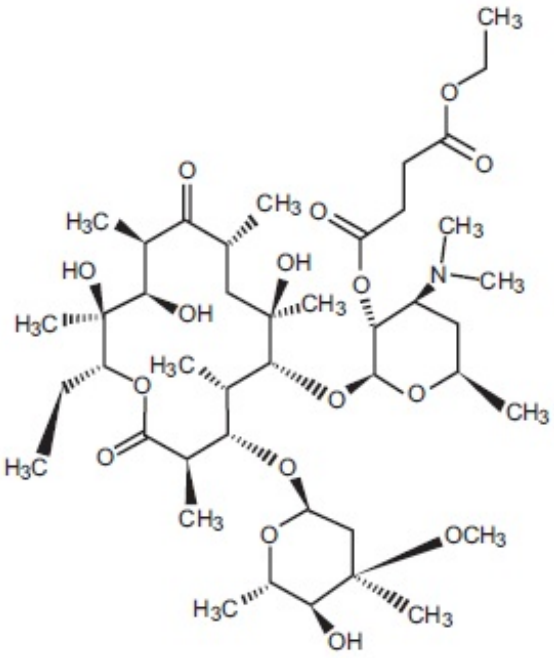
ERYTHROMYCIN ETHYLSUCCINATE- erythromycin suspension
Amneal Pharmaceuticals NY LLC

Erythromycin Ethylsuccinate for Oral Suspension, USP
200 mg/5 mL and 400 mg/5 mL
Rx only

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

DESCRIPTION

Erythromycin, USP is produced by a strain of *Saccharopolyspora erythraea* (formerly *Streptomyces erythraeus*) and belongs to the macrolide group of antibiotics. It is basic and readily forms salts with acids. The base, the stearate salt, and the esters are poorly soluble in water. Erythromycin ethylsuccinate, USP is an ester of erythromycin, USP suitable for oral administration. Erythromycin ethylsuccinate, USP is known chemically as erythromycin 2'-(ethyl succinate). The molecular formula is $C_{43}H_{75}NO_{16}$ and the molecular weight is 862.05 g/mol. The structural formula is:



Erythromycin ethylsuccinate for oral suspension, USP, 200 mg/5 mL when reconstituted with water, forms a suspension containing erythromycin ethylsuccinate, USP equivalent to 200 mg erythromycin per 5 mL (teaspoonful) or 100 mg per 2.5 mL (dropperful) with an appealing fruit flavor. Erythromycin ethylsuccinate for oral suspension, USP, 400 mg/5 mL when reconstituted with water, forms a suspension containing erythromycin ethylsuccinate, USP equivalent to 400 mg of erythromycin per 5 mL (teaspoonful) with

an appealing banana flavor.

These products are intended primarily for pediatric use but can also be used in adults.

Inactive Ingredients

Erythromycin ethylsuccinate for oral suspension, USP, 200 mg/5 mL contains caramel flavor, mixed fruit flavor, polysorbate 80, sodium citrate dihydrate, sucrose, and xanthan gum. Erythromycin ethylsuccinate for oral suspension, USP 400 mg/5 mL contains banana flavor, caramel flavor, polysorbate 80, sodium citrate dihydrate, sucrose, and xanthan gum.

CLINICAL PHARMACOLOGY

Orally administered erythromycin ethylsuccinate suspension is readily and reliably absorbed under both fasting and nonfasting conditions.

Erythromycin diffuses readily into most body fluids. Only low concentrations are normally achieved in the spinal fluid, but passage of the drug across the blood-brain barrier increases in meningitis. In the presence of normal hepatic function, erythromycin is concentrated in the liver and excreted in the bile; the effect of hepatic dysfunction on excretion of erythromycin by the liver into the bile is not known. Less than 5 percent of the orally administered dose of erythromycin is excreted in active form in the urine.

Erythromycin crosses the placental barrier, but fetal plasma levels are low. The drug is excreted in human milk.

Microbiology:

Erythromycin acts by inhibition of protein synthesis by binding 50 *S* ribosomal subunits of susceptible organisms. It does not affect nucleic acid synthesis. Antagonism has been demonstrated *in vitro* between erythromycin and clindamycin, lincomycin, and chloramphenicol.

Many strains of *Haemophilus influenzae* are resistant to erythromycin alone but are susceptible to erythromycin and sulfonamides used concomitantly.

Staphylococci resistant to erythromycin may emerge during a course of therapy.

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

Gram-positive Organisms:

Corynebacterium diphtheriae

Corynebacterium minutissimum

Listeria monocytogenes

Staphylococcus aureus (resistant organisms may emerge during treatment)

Streptococcus pneumoniae

Streptococcus pyogenes

Gram-negative Organisms:

Bordetella pertussis

Legionella pneumophila

Neisseria gonorrhoeae

Other Microorganisms:

Chlamydia trachomatis

Entamoeba histolytica

Mycoplasma pneumoniae

Treponema pallidum

Ureaplasma urealyticum

The following *in vitro* data are available.

Erythromycin exhibits *in vitro* minimal inhibitory concentrations (MIC's) of 0.5 mcg/mL or less against most (≥ 90%) strains of the following microorganisms; however, the safety and effectiveness of erythromycin in treating clinical infections due to these microorganisms have not been established in adequate and well-controlled clinical trials.

Gram-positive Organisms:

Viridans group streptococci

Gram-negative Organisms:

Moraxella catarrhalis

Susceptibility Tests:

For specific information regarding susceptibility test interpretive criteria and associated test methods and quality control standards recognized by FDA for this drug, please see: https://www.fda.gov/STIC.

INDICATIONS AND USAGE

To reduce the development of drug-resistant bacteria and maintain the effectiveness of erythromycin ethylsuccinate for oral suspension and other antibacterial drugs, erythromycin ethylsuccinate for oral suspension should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of

therapy.

Erythromycin ethylsuccinate for oral suspension is indicated in the treatment of infections caused by susceptible strains of the designated organisms in the diseases listed below:

Upper respiratory tract infections of mild to moderate degree caused by *Streptococcus pyogenes*, *Streptococcus pneumoniae*, or *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 pneumoniae* or *Streptococcus pyogenes*.

Listeriosis caused by *Listeria monocytogenes*.

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.

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).

Diphtheria: Infections 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 infections due to *Corynebacterium minutissimum*.

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

Acute Pelvic Inflammatory Disease Caused by *Neisseria gonorrhoeae*: 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.

Syphilis Caused by *Treponema pallidum*: Erythromycin is an alternate choice of treatment for primary syphilis in penicillin-allergic patients. In primary syphilis, spinal fluid examinations should be done before treatment and as part of follow-up after therapy.

Erythromycins are indicated for the 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*.

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.

Prophylaxis:

Prevention of Initial Attacks of Rheumatic Fever:

Penicillin is considered by the American Heart Association to be the drug of choice in the prevention of initial attacks of rheumatic fever (treatment of *Streptococcus pyogenes* infections of the upper respiratory tract, e.g., tonsillitis or pharyngitis). Erythromycin is indicated for the treatment of penicillin-allergic patients.[4] The therapeutic dose should be administered for 10 days.

Prevention of Recurrent Attacks of Rheumatic Fever:

Penicillin or sulfonamides are considered by the American Heart Association to be the drugs of choice in the prevention of recurrent attacks of rheumatic fever. In patients who are allergic to penicillin and sulfonamides, oral erythromycin is recommended by the American Heart Association in the long-term prophylaxis of Streptococcal pharyngitis (for the prevention of recurrent attacks of rheumatic fever).[4]

CONTRAINDICATIONS

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

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

Do not use erythromycin concomitantly with HMG CoA reductase inhibitors (statins) that are extensively metabolized by CYP 3A4 (lovastatin or simvastatin), due to the increased risk of myopathy, including rhabdomyolysis.

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:

Erythromycin has been associated with prolongation of the QT interval and infrequent cases of arrhythmia. Cases of torsades de pointes have been spontaneously reported during post-marketing surveillance in patients receiving erythromycin. Fatalities 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, sotalol) 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:

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including erythromycin ethylsuccinate, 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 hypotension with calcium channel blockers metabolized by CYP3A4 (e.g., verapamil, amlodipine, 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 erythromycin ethylsuccinate 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** sections).

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

There have been reports of infantile hypertrophic pyloric stenosis (IHPS) occurring in infants following erythromycin therapy. In one cohort of 157 newborns who were given erythromycin for pertussis prophylaxis, seven neonates (5%) developed symptoms of non-bilious vomiting or irritability with feeding and were subsequently diagnosed as having IHPS requiring surgical *pyloromyotomy*. A possible dose-response effect was described with an absolute risk of IHPS of 5.1% for infants who took erythromycin for 8 days to 14 days and 10% for infants who took erythromycin for 15 days to 21 days.[5] Since erythromycin may be used in the treatment of conditions in infants which are associated with significant mortality or morbidity (such as pertussis or neonatal *Chlamydia trachomatis* infections), the benefit of erythromycin therapy needs to be weighed against the potential risk of developing IHPS. Parents should be informed to contact their physician if vomiting or irritability with feeding occurs. Prolonged or repeated use of erythromycin may result in an overgrowth of nonsusceptible bacteria or fungi. If superinfection occurs, erythromycin should be discontinued and appropriate therapy instituted.

When indicated, incision and drainage or other surgical procedures should be performed in conjunction with antibiotic therapy. Observational studies in humans have reported cardiovascular malformations after exposure to drug products containing erythromycin during early pregnancy.

Information for Patients:

Patients should be counseled that antibacterial drugs including erythromycin ethylsuccinate should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When erythromycin ethylsuccinate is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by erythromycin ethylsuccinate or other antibacterial drugs in the future.

Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, patients should contact their physician as soon as possible.

Drug Interactions

Theophylline:

Erythromycin use in patients who are receiving high doses of theophylline may be associated with an increase in serum theophylline levels and potential theophylline toxicity. In case of theophylline toxicity and/or elevated serum theophylline levels, the dose of theophylline should be reduced while the patient is receiving concomitant erythromycin therapy.

There have been published reports suggesting that when oral erythromycin is given concurrently with theophylline there is a decrease in erythromycin serum concentrations of approximately 35%. The mechanism by which this interaction occurs is unknown. The decrease in erythromycin concentrations due to co-administration of theophylline could result in subtherapeutic concentrations of erythromycin.

Hypotension, bradyarrhythmias, and lactic acidosis have been observed in patients receiving concurrent verapamil, belonging to the calcium channel blockers drug class.

Concomitant administration of erythromycin and digoxin has been reported to result in elevated digoxin serum levels. There have been reports of increased anticoagulant effects when erythromycin and oral anticoagulants were used concomitantly. Increased anticoagulation effects due to interactions of erythromycin with various oral anticoagulants may be more pronounced in the elderly.

Erythromycin is a substrate and inhibitor of the 3A isoform subfamily of the cytochrome p450 enzyme system (CYP3A). Co-administration of erythromycin and a drug primarily metabolized by CYP3A may be associated with elevations in drug concentrations that could increase or prolong both the therapeutic and adverse effects of the concomitant drug. Dosage adjustments may be considered, and when possible, serum concentrations of drugs primarily metabolized by CYP3A should be monitored closely in patients concurrently receiving erythromycin.

The following are examples of some clinically significant CYP3A based drug interactions. Interactions with other drugs metabolized by the CYP3A isoform are also possible. The following CYP3A based drug interactions have been observed with erythromycin products in post-marketing experience:

Ergotamine/dihydroergotamine:

Post-marketing reports indicate that co-administration of erythromycin with ergotamine or dihydroergotamine has been associated with acute ergot toxicity characterized by vasospasm and ischemia of the extremities and other tissues including the central nervous system. Concomitant administration of erythromycin with ergotamine or dihydroergotamine is contraindicated (see **CONTRAINDICATIONS**).

Triazolobenzodiazepines: (such as triazolam and alprazolam) and *Related Benzodiazepines:*

Erythromycin has been reported to decrease the clearance of triazolam and midazolam, and thus, may increase the pharmacologic effect of these benzodiazepines.

HMG-CoA Reductase Inhibitors:

Erythromycin has been reported to increase concentrations of HMG-CoA reductase inhibitors (e.g., lovastatin and simvastatin). Rare reports of rhabdomyolysis have been reported in patients taking these drugs concomitantly.

Sildenafil (Viagra):

Erythromycin has been reported to increase the systemic exposure (AUC) of sildenafil. Reduction of sildenafil dosage should be considered. (See Viagra package insert.)

There have been spontaneous or published reports of CYP3A based interactions of erythromycin with cyclosporine, carbamazepine, tacrolimus, alfentanil, disopyramide, rifabutin, quinidine, methylprednisolone, cilostazol, vinblastine, and bromocriptine.

Concomitant administration of erythromycin with cisapride, pimozide, astemizole, or terfenadine is contraindicated (see **CONTRAINDICATIONS**).

In addition, there have been reports of interactions of erythromycin with drugs not thought to be metabolized by CYP3A, including hexobarbital, phenytoin, and valproate.

Erythromycin has been reported to significantly alter the metabolism of the nonsedating antihistamines terfenadine and astemizole when taken concomitantly. Rare cases of serious cardiovascular adverse events, including electrocardiographic QT/QTc interval prolongation, cardiac arrest, torsades de pointes, and other ventricular arrhythmias have been observed (see **CONTRAINDICATIONS**). In addition, deaths have been reported rarely with concomitant administration of terfenadine and erythromycin.

There have been post-marketing reports of drug interactions when erythromycin was co-administered with cisapride, resulting in QT prolongation, cardiac arrhythmias, ventricular tachycardia, ventricular fibrillation, and torsades de pointes most likely due to the inhibition of hepatic metabolism of cisapride by erythromycin. Fatalities have been reported (see **CONTRAINDICATIONS**).

Colchicine:

Colchicine is a substrate for both CYP3A4 and the efflux transporter P-glycoprotein (P-gp). Erythromycin is considered a moderate inhibitor of CYP3A4. A significant increase in colchicine plasma concentration is anticipated when co-administered with moderate CYP3A4 inhibitors such as erythromycin. If co-administration of colchicine and erythromycin is necessary, the starting dose of colchicine may need to be reduced, and the maximum colchicine dose should be lowered. Patients should be monitored for clinical symptoms of colchicine toxicity (see **WARNINGS**).

Drug/Laboratory Test Interactions:

Erythromycin interferes with the fluorometric determination of urinary catecholamines.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Long-term oral dietary studies conducted with erythromycin stearate in rats up to 400 mg/kg/day and in mice up to 500 mg/kg/day (approximately 1 fold to 2 fold of the maximum human dose on a body surface area basis) did not provide evidence of tumorigenicity. Erythromycin stearate did not show genotoxic potential in the Ames, and mouse lymphoma assays or induce chromosomal aberrations in CHO cells. There was no apparent effect on male or female fertility in rats treated with erythromycin base by oral gavage at 700 mg/kg/day (approximately 3 times the maximum human dose on a body surface area basis).

Pregnancy:

Teratogenic Effects. *Pregnancy Category B:* There is no evidence of teratogenicity or any other adverse effect on reproduction in female rats fed erythromycin base by oral gavage at 350 mg/kg/day (approximately twice the maximum recommended human dose on a body surface area) prior to and during mating, during gestation, and through weaning. No evidence of teratogenicity or embryotoxicity was observed when erythromycin base was given by oral gavage to pregnant rats and mice at 700 mg/kg/day and to pregnant rabbits at 125 mg/kg/day (approximately 1 time to 3 times the maximum recommended human dose).

Labor and Delivery:

The effect of erythromycin on labor and delivery is unknown.

Nursing Mothers:

Erythromycin is excreted in human milk. Caution should be exercised when erythromycin is administered to a nursing woman.

Pediatric Use:

See **INDICATIONS AND USAGE** and **DOSAGE AND ADMINISTRATION** sections.

Geriatric Use:

Elderly patients, particularly those with reduced renal or hepatic function, may be at increased risk for developing erythromycin-induced hearing loss (see **ADVERSE REACTIONS** and **DOSAGE AND ADMINISTRATION**).

Elderly patients may be more susceptible to development of torsades de pointes arrhythmias than younger patients (see **WARNINGS**).

Elderly patients may experience increased effects of oral anticoagulant therapy while undergoing treatment with erythromycin (see **PRECAUTIONS - Drug Interactions**).

Erythromycin ethylsuccinate for oral suspension, 200 mg/5 mL contains 116.1 mg (5.0 mEq) of sodium per individual dose.

Erythromycin ethylsuccinate for oral suspension, 400 mg/5 mL contains 116.1 mg (5.0 mEq) of sodium per individual dose.

Based on the 200 mg/5 mL strength, at the usual recommended doses, adult patients would receive a total of 928.8 mg/day (40.4 mEq) of sodium.

Based on the 400 mg/5 mL strength, at the usual recommended doses, adult patients would receive a total of 464.4 mg/day (20.2 mEq) of sodium. The geriatric population may respond with a blunted natriuresis to salt loading. This may be clinically important with regard to such diseases as congestive heart failure.

ADVERSE REACTIONS

The most frequent side effects of oral erythromycin preparations are gastrointestinal and are dose-related. They include nausea, vomiting, abdominal pain, diarrhea and anorexia. Symptoms of hepatitis, hepatic dysfunction and/or abnormal liver function test results may occur (see **WARNINGS** section).

Onset of pseudomembranous colitis symptoms may occur during or after antibacterial treatment (see **WARNINGS**).

Erythromycin has been associated with QT prolongation and ventricular arrhythmias, including ventricular tachycardia and torsades de pointes (see **WARNINGS**).

Allergic reactions ranging from urticaria to anaphylaxis have occurred. Skin reactions ranging from mild eruptions to erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported rarely.

There have been reports of interstitial nephritis coincident with erythromycin use.

There have been rare reports of pancreatitis and convulsions.

There have been isolated reports of reversible hearing loss occurring chiefly in patients with renal insufficiency and in patients receiving high doses of erythromycin.

To report SUSPECTED ADVERSE REACTIONS, contact Amneal Pharmaceuticals at 1-877-835-5472 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

OVERDOSAGE

In case of overdosage, erythromycin should be discontinued. Overdosage should be handled with the prompt elimination of unabsorbed drug and all other appropriate measures should be instituted.

Erythromycin is not removed by peritoneal dialysis or hemodialysis.

DOSAGE AND ADMINISTRATION

Erythromycin ethylsuccinate for oral suspension may be administered without regard to meals.

Children:

Age, weight, and severity of the infection are important factors in determining the proper dosage. In mild to moderate infections, the usual dosage of erythromycin ethylsuccinate for children is 30 mg/kg/day to 50 mg/kg/day in equally divided doses every 6 hours. For more severe infections this dosage may be doubled. If twice-a-day dosage is desired, one-half of the total daily dose may be given every 12 hours. Doses may also be given three times daily by administering one-third of the total daily dose every 8 hours.

The following dosage schedule is suggested for mild to moderate infections:

Body Weight	**Total Daily Dose**
Under 10 lbs	30 to 50 mg/kg/day 15 to 25 mg/lbs/day
10 to 15 lbs	200 mg
16 to 25 lbs	400 mg
26 to 50 lbs	800 mg
51 to 100 lbs	1,200 mg
over 100 lbs	1,600 mg

Adults:

400 mg erythromycin ethylsuccinate every 6 hours is the usual dose. Dosage may be increased up to 4 g per day according to the severity of the infection. If twice-a-day dosage is desired, one-half of the total daily dose may be given every 12 hours. Doses may also be given three times daily by administering one-third of the total daily dose every 8 hours.

For adult dosage calculation, use a ratio of 400 mg of erythromycin activity as the ethylsuccinate to 250 mg of erythromycin activity as the stearate, base or estolate.

In the treatment of streptococcal infections, a therapeutic dosage of erythromycin ethylsuccinate should be administered for at least 10 days. In continuous prophylaxis against recurrences of streptococcal infections in persons with a history of rheumatic heart disease, the usual dosage is 400 mg twice a day.

For treatment of urethritis due to *C. trachomatis* or *U. urealyticum*: 800 mg three times a day for 7 days.

For treatment of primary syphilis: Adults: 48 g to 64 g given in divided doses over a period of 10 days to 15 days.

For intestinal amebiasis: Adults: 400 mg four times daily for 10 days to 14 days. Children: 30 mg/kg/day to 50 mg/kg/day in divided doses for 10 days to 14 days.

For use in pertussis: Although optimal dosage and duration have not been established, doses of erythromycin utilized in reported clinical studies were 40 mg/kg/day to 50 mg/kg/day, given in divided doses for 5 days to 14 days.

For treatment of Legionnaires' Disease: Although optimal doses have not been established, doses utilized in reported clinical data were 1.6 g to 4 g daily in divided doses.

HOW SUPPLIED

Erythromycin ethylsuccinate for oral suspension, USP, **200 mg/5 mL**, dry powder is supplied as white to off-white granules. Reconstituted suspension is off-white to light pink colored suspension.

It is available as follows:

100 mL Bottles (when mixed): NDC 60219-1503-1

Erythromycin ethylsuccinate for oral suspension, USP, **400 mg/5 mL**, dry powder is supplied as white to off-white granules. Reconstituted suspension is off-white to light pink colored suspension.

It is available as follows:

100 mL Bottles (when mixed): NDC 60219-1504-2

Recommended Storage:

Store erythromycin ethylsuccinate for oral suspension, USP, 200 mg/5 mL and 400 mg/5 mL, prior to mixing, below 86°F (30°C). After reconstitution, erythromycin ethylsuccinate for oral suspension, USP, 200 mg/5 mL and 400 mg/5 mL must be stored at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature] and used within 35 days; refrigeration is not required.

REFERENCES

4. Committee on Rheumatic Fever, Endocarditis, and Kawasaki Disease of the Council on Cardiovascular Disease in the Young, the American Heart Association: Prevention of Rheumatic Fever. Circulation. 78(4):1082-1086, October 1988.

5. Honein, M.A., et. al.: Infantile hypertrophic pyloric stenosis after pertussis prophylaxis with erythromycin: a case review and cohort study. The Lancet 1999;354 (9196): 2101-5

Manufactured by:

Amneal Pharmaceuticals Pvt. Ltd.

Ahmedabad 382220, INDIA

Distributed by:

Amneal Pharmaceuticals LLC

Bridgewater, NJ 08807

Rev. 01-2024-01

PRINCIPAL DISPLAY PANEL

NDC 60219-1503-1

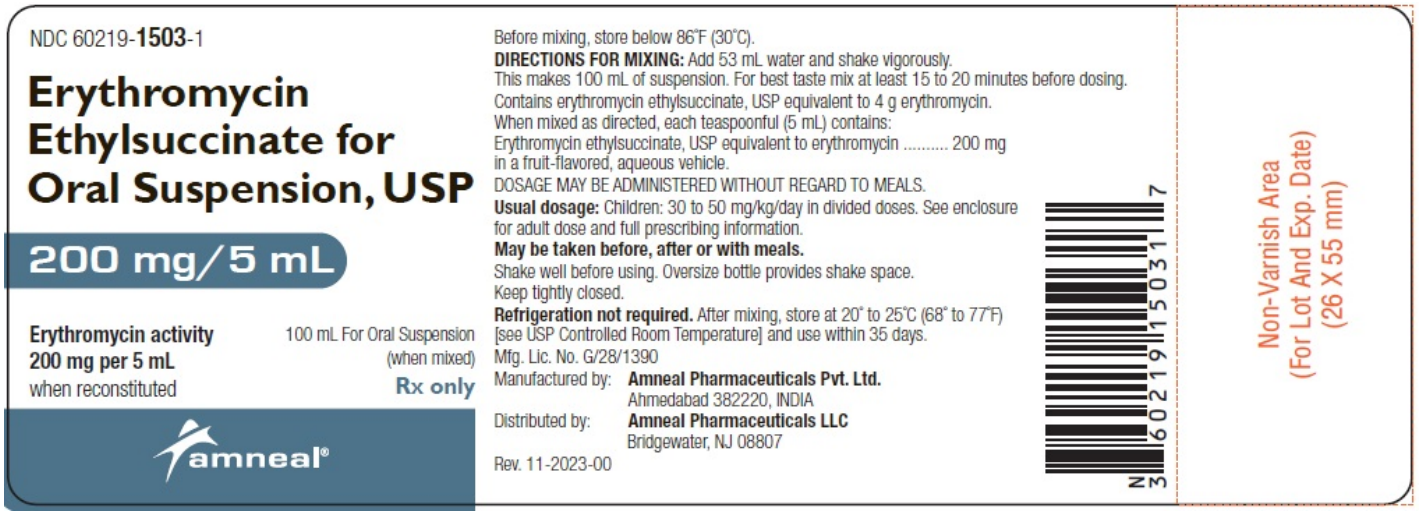
Erythromycin Ethylsuccinate for Oral Suspension, USP

200 mg/5 mL

Bottle Label

Rx only

Amneal Pharmaceuticals LLC



NDC 60219-1504-1

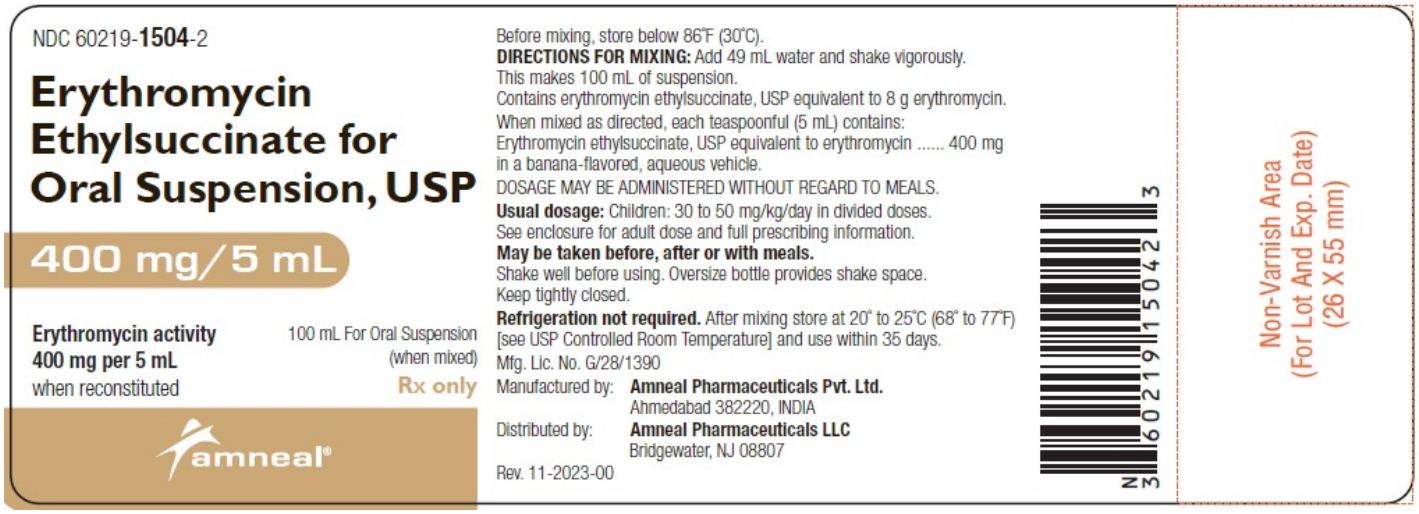
Erythromycin Ethylsuccinate for Oral Suspension, USP

400 mg/5 mL

Bottle Label

Rx only

Amneal Pharmaceuticals LLC



ERYTHROMYCIN ETHYLSUCCINATE

erythromycin suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60219-1503
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ERYTHROMYCIN ETHYLSUCCINATE (UNII: 1014KSJ86F) (ERYTHROMYCIN - UNII:63937KV33D)	ERYTHROMYCIN	200 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Product Characteristics			
Color	white (White to off-white granules)	**Score**	
Shape		**Size**	
Flavor	FRUIT (mixed-fruit flavor) , CARAMEL	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60219-1503-1	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211204	12/02/2023	

ERYTHROMYCIN ETHYLSUCCINATE

erythromycin suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60219-1504
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ERYTHROMYCIN ETHYLSUCCINATE (UNII: 1014KSJ86F) (ERYTHROMYCIN - UNII:63937KV33D)	ERYTHROMYCIN	400 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Product Characteristics

Color	white (White to off-white granules)	**Score**	
Shape		**Size**	
Flavor	BANANA, CARAMEL	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60219-1504-2	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211204	12/02/2023	

Labeler - Amneal Pharmaceuticals NY LLC (123797875)

Establishment

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals Private Limited		915076126	analysis(60219-1503, 60219-1504) , label(60219-1503, 60219-1504) , manufacture(60219-1503, 60219-1504) , pack(60219-1503, 60219-1504)

Revised: 4/2025 Amneal Pharmaceuticals NY LLC