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Product : T - ERYSON GRANULES [FRONT] SAP No. : Date : 28 July 2025	☐ Unit Box ☑ Leaflet ☐ Aluminium Foil ☐ Generic Box ☐ Outer Box ☐ Fix-A-Form ☐ Sachet ☐ Label ☐ Shipper Carton ☐ Others : _____	

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1. Font : Adobe Garamond Pro (Spacing - 6.3pt / Size - 7.56pt) 2. Dimension : 170mm(w) x 242mm (h)	Black Colours shown on this proof are to indicate correct colour separations.

Eryson Granules 200mg/5ml

Eryson Granules 400mg/5ml

DESCRIPTION

Eryson Granules 200mg/5ml

An almost white powder when reconstituted forms a pink, fruity flavoured, homogenous suspension.
Each 5 mL contains Erythromycin Ethylsuccinate equivalent to Erythromycin 200 mg.
Preservatives: Methylparaben 0.167% w/v and Propylparaben 0.031% w/v

Eryson Granules 400mg/5ml

An almost white powder when reconstituted forms a pink, fruity flavoured, homogenous suspension.
Each 5 mL contains Erythromycin Ethylsuccinate equivalent to Erythromycin 400 mg.
Preservatives: Methylparaben 0.167% w/v and Propylparaben 0.031% w/v

INDICATIONS

Bronchitis, enteritis, venereal diseases, diphtheria, Legionella infections, pertussis, pneumonia, sinusitis. Prophylaxis of surgical infections, prophylaxis of endocarditis, pharyngitis, perinatal streptococcal infections, rheumatic fever. Alternative to tetracyclines in Lyme disease, chlamydial & rickettsial infections, severe acne. Otitis media, erythrasma, listeriosis, diphtheria, primary syphilis in patients allergy to penicillin.

PHARMACODYNAMICS

Erythromycin is thought to penetrate the bacterial cell membrane and to reversibly bind to the 50S subunit of bacterial ribosomes; it does not directly inhibit peptide formation, but rather inhibits the translocation of peptides from the acceptor site on the ribosome to the donor site, inhibiting subsequent protein synthesis and hence cell growth. Erythromycin is effective only against actively dividing organisms. Because of the ready penetration of macrolides into white blood cells and macrophages there has been some interest in their potential synergy with host defence mechanisms in vivo.
Its actions are increased at moderately alkaline pH (up to about 8.5), particularly in Gram-negative species, probably because of the improved cellular penetration of the nonionised form of the drug.

PHARMACOKINETICS

Erythromycin base is unstable in gastric acid, and absorption is therefore variable and unreliable. In consequence, the base is usually administered in film or enteric-coated preparations, or one of the more acid-stable salts or esters is employed.
Food may reduce the absorption of the base or the stearate (as in Eryson 250 Tablet), although this depends to some extent on the formulation. The ethylsuccinate ester (as in Eryson Granules) is generally more reliably and quickly absorbed and their absorption is little better when taken with meals.
Peak plasma concentrations generally occur between 1-4 hours after administration, and have been reported to range between 0.3-0.5 mcg/mL after 250 mg of erythromycin stearate or 500 mg of ethylsuccinate. Fifty-five percent of ethylsuccinate is present as the active base the rest being present as the ester. Erythromycin is widely distributed throughout body tissues and fluids, including middle ear exudate, prostatic fluid, and semen. Highest concentrations are found in the liver bile and spleen. Some is taken up into polymorphonuclear lymphocytes and macrophages. Low concentrations are found in the cerebrospinal fluid (CSF) as it does not cross the blood-brain barrier well; however, penetrations into CSF increases with meningeal inflammation. Around 70% of the base is protein bound. Erythromycin crosses the placenta; foetal concentrations are variously stated to be 5%-20% of those in the mother. It is distributed into breast milk. Erythromycin stearate dissociates into erythromycin base in the duodenum.
More than 90% of a dose is hepatically metabolised, particularly to inactive metabolites; accumulation may occur in patients with severe hepatic disease.
Erythromycin ethylsuccinate, on the other hand, is absorbed into the blood and is hydrolysed to erythromycin base in the gastrointestinal tract and in the blood to produce 56%-69% of the dose as base in the serum.
The half-life of erythromycin is usually reported to be in the range of 1.5-2.5 hours, although this increase to about 5 hours in anuric patients. Erythromycin is excreted primarily into the bile and 2%-5% of an oral dose is excreted unchanged in the urine. It is not removed by hemodialysis or peritoneal dialysis.

DOSAGE

Eryson Granules 200mg/5mL	Eryson Granules 400mg/5mL
Adults Adults: 400mg (10ml), 6 hourly or 800mg (20ml), 12 hourly. Dosage may be increased up to 4g per day according to the severity of the infection.	**Adults** Adults: 400mg (5ml), 6 hourly or 800mg (10ml), 12 hourly. Dosage may be increased up to 4g per day according to the severity of the infection.
Children • Children: 30-50mg/kg daily in divided doses; double in severe infections. • Children 2 to 8 years: 1g (25ml) daily in divided doses. • Infant and children < 2 years: 500mg (12.5ml) daily in divided doses	**Children** • Children 30-50mg/kg daily in divided doses; double in severe infections. • Children 2 to 8 years: 1g (12.5ml) daily in divided doses. • Infant and children < 2 years: 500mg (6.25ml) daily in divided doses

OVERDOSAGE

There is no specific antidote for the treatment of erythromycin overdose. Treatment should be symptomatic and supportive and includes the following:

a) Administering epinephrine, corticosteroids, and antihistamines for allergic reactions.
b) Evacuating the stomach to eliminate unabsorbed drug.
c) Using supportive measures as needed.

Up-to-date information on treatment of overdose can be obtained from
The National Poison Centre, University Sains Malaysia

TOXICOLOGY

Cross sensitivity and/or related problems
Patients intolerant of one erythromycin or other macrolides may be intolerant of other erythromycins also.

Tumorigenicity and Mutagenicity
Long term (20 months) oral studies done in rats did not demonstrate erythromycin base to be tumorigenic. Mutagenicity studies have not been conducted.

Pregnancy and Reproduction
Fertility
Adequate and well-controlled studies in human have not been done. Studies in rats fed erythromycin base at concentrations up to 0.25% of their diet found no apparent effect on male or female fertility.
Pregnancy
Erythromycin crosses the placenta, resulting in low fetal plasma concentrations (5%-20% of maternal plasma concentrations). Erythromycin estolate has been associated with an increased risk of reversible, subclinical hepatotoxicity in approximately 10% of pregnant women; its use during pregnancy is not recommended. However, problem with other erythromycin have not be documented . There was no evidence of teratogenicity or any other adverse effect on reproduction in female rats fed erythromycin base (up to 0.25% of their diet) prior to and during mating, during gestation, and through weaning of 2 successive litters. (FDA Pregnancy Category B)

Breast-feeding
Erythromycins are distributed into breast milk. However, problems in human have not been documented.

Pediatric
Studies performed to date have not demonstrated pediatrics-specific problems that would limit the usefulness of erythromycin in children.

Geriatrics
Studies performed to date have not demonstrated geriatrics-specific problems that would limit the usefulness of erythromycin in the elderly. However, elderly patients may be at increased risk of hearing loss if they also have decreased renal or hepatic function associated with aging and are receiving high doses of erythromycin.

Dental
Systemic erythromycins may lead to oral candidiasis in patients undergoing long-term therapy.

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SIDE EFFECTS

Erythromycin and its salts and esters are generally well tolerated. Gastrointestinal effects such as abdominal discomfort and cramp, nausea, vomiting and diarrhoea are fairly common. These effects are dose-related and appear to be more common in young than in older subjects.

Oral candidiasis (sore mouth or tongue, white patches in mouth and/or on tongue), vaginal candidiasis (vaginal itching and discharge),supra-infection with resistant organisms may occur and pseudomembranous colitis has also been reported. Hypersensitivity reactions appear to be uncommon, with symptoms such as pruritus, urticaria and skin rash as well as occasional cases of anaphylaxis. A hypersensitivity reaction may also be responsible for the hepatotoxicity. Symptoms indicative of cholestasis, including upper abdominal pain (sometimes very severe), nausea and vomiting, abnormal liver function values, raised serum bilirubin and usually jaundice, may be accompanied by skin rashes, fever, unusual tiredness or weakness and eosinophilia. Symptoms usually occur initially in patients who have been receiving the drug for more than 10 days, although they may develop more quickly in patients given the drug in a previous course of treatment. Hepatotoxicity occurs more frequently with erythromycin estolate. The effects erythromycin in the liver are generally reversible on discontinuing treatment.

Rare adverse effects reported include reversible sensorineural deafness, sometimes with tinnitus. These effects apear to be related to serum concentration with an increased likelihood of such effects in patients given doses of 4g or more daily of base or its equivalent, and in those with renal or hepatic impairment and/or- in elderly patients.

Cardiac toxicity, especially QT prolongation and torsade de pointes (irregular or slow heart rate, recurrent fainting, sudden death), agranulocytosis, central neurotoxicity including psychotic reactions and nightmares, a myasthenia-like syndrome and pancreatitis occurs rarely.

Postmarketing Experience;

Gastrointestinal Disorders: infantile hypertrophic pyloric stenosis.

Skin and Subcutaneous Tissue Disorders

Frequency not known: severe cutaneous adverse reaction (SCARs) including Stevens-Johnson Syndrom (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) & acute generalised exanthematous pustulosis (AGEP)

CONTRAINDICATIONS

Patients hypersensitive to erythromycin and its derivatives and those who have previously developed liver disorders while receiving erythromycins should not be given the drug.

Patients with a history of cardiac arrhythmias or QT prolongation may be at risk for arrhythmias or torsade de pointes while receiving high doses of erythromycin. Patients with a history of hearing loss may be at increased risk of further hearing loss especially if the patient has renal or hepatic function impairment, is elderly and is receiving high doses of erythromycin.

DRUG INTERACTIONS

Potentiation and sometimes toxicity has been reported for a number of drugs when erythromycin was given concomitantly; in some cases, this may be due to reduced metabolism because the effects of erythromycin on cytochrome P-450. Among the agents reported to be affected by erythromycin are alfentanil, astemizole, bromocriptine, carbamazepine, cyclosporin, digoxin, disopyramide, ergotamine, lovastatin, methylprednisolone, midazolam, nicoumalone, phenytoin, quinidine, tacrolimus, theophylline and other xanthines, triazolam, valproic acid, warfarin and zopiclone. Erythromycin should be given with caution if other hepatotoxic or ototoxic drugs are given concomitantly. Cimetidine might increase the risk of toxicity. Erythromycins may displace chloramphenicol or lincomycins from, or prevent them from binding to 50S subunits of bacterial ribosomes, thus antagonizing the effects of these drugs; concurrent use is not recommended. Rare cases of serious cardiovascular adverse event including deaths, cardiac arrests, torsade de pointes and other ventricular arrhythmia have been observed when used in patients taking concomitant terfenadine. Since bacteriostatic drugs may interfere with the bactericidal effect of penicillins in the treatment of meningitis or in situations where a rapid bactericidal effect is necessary, it is best to avoid concurrent therapy.

PRECAUTIONS

Erythromycin should be used with care in patients with existing liver disease or hepatic function impairment. Hepatic function determinations may be required periodically if signs of hepatic dysfunction occur with any of the erythromycins. Erythromycins should be discontinued promptly if signs of hepatic dysfunction occur. It has been suggested that erythromycin should be used with care in patients with a history of arrhythmias. Monitoring of QT interval is recommended in such patients. Erythromycins may interfere with some diagnostic tests including measurements of 17-hydroxycorticosteroids. It may also produce false elevations of urinary catecholamines because of interference with the fluorometric determination. Physiology/ laboratory test values of alanine aminotransferase (ALT [SGPT]), alkaline phosphatase (ALP), aspartate aminotransferase (AST [SGOT]) and serum bilirubin may be increased by all erythromycins, but more commonly by erythromycin estolate.

There have been reports of infantile hyperthropic ploric stenosis (IHPS) occuring 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. Since erythromycin may be used in the treatment of conditions in infants which are associated with significant mortality or morbidity (such as pertussis or chlamydia), the benefit of erythromycin therapy needs to be weighed against the potential risk of developing IHPS. Parents and caregivers should be informed to contact their physician if vomiting and/or irritability with feeding occurs.

In the event of severe acute hypersensitivity reactions, such as anaphylaxis, severe cutaneous adverse reaction (SCARs) [e.g. Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) & acute generalised exanthematous pustulosis (AGEP)]. Eryson Granules 200 & Eryson Granules 400 should be discontinued immediately and appropriate treatment should be urgently initiated.

PRESENTATION

Eryson Granules 200mg/5ml } 60ml & 100ml.
Eryson Granules 400mg/5ml } 60 mL x 5 bottles & 60ml.
Not all pack size are available locally

STORAGE CONDITIONS AND USER INSTRUCTIONS

Keep container tightly closed (granules only)
Store in a dry place below 30°C.
Protect from light.
Keep out of reach of children.
Jauhi daripada kanak-kanak.
Shelf life: Please refer to outer package.
First, shake the bottle to loosen the powder. Add approximately 2 tablespoons of water, invert the bottle and shake vigorously for about 15 seconds. Then, add water to make up to the mark.
Shake well before each dose. Store tightly closed in the refrigerator (2-8°C) after reconstitution. Discard 7 days after reconstitution.
Route of Administration: Oral

Product Registration Holder:
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DUOPHARMA

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