SUMMARY OF PRODUCT CHARACTERISTICS
ERYSTAR-500 (Erythromycin Stearate Tablets 500 mg)

1. NAME OF THE MEDICINAL PRODUCT

ERYSTAR-500 (Erythromycin Stearate Tablets 500 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 500 mg erythromycin stearate BP, equivalent to 500 mg erythromycin.

Excipients with known effect:

Contains erythrosine (E127) as a colouring agent. For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

Pink coloured, caplet shaped, biconvex, film-coated tablet with a break-line on one side and plain on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the prophylaxis and treatment of infections caused by erythromycin-sensitive organisms.

Erythromycin is highly effective in the treatment of a variety of clinical infections, including:

- Upper respiratory tract infections: laryngitis, pharyngitis, sinusitis, secondary infections in colds and influenza, tonsillitis, peritonsillar abscess.
- Lower respiratory tract infections: acute and chronic bronchitis, tracheitis, pneumonia (lobar pneumonia, bronchopneumonia, primary atypical pneumonia), bronchiectasis, Legionnaire's disease.
- Eye infections: blepharitis.
- Ear infections: otitis media and otitis externa, mastoiditis.
- Oral infections: gingivitis, Vincent's angina.
- Skin and soft tissue infections: boils and carbuncles, abscesses, pustular acne, paronychia, impetigo, cellulitis, erysipelas.
- Gastrointestinal infections: staphylococcal enterocolitis, cholecystitis.
- Other infections: gonorrhoea, syphilis, urethritis, osteomyelitis, lymphogranuloma venereum, diphtheria, prostatitis, scarlet fever.
- Prophylaxis: pre- and post-operative, burns, trauma, rheumatic fever.

4.2 Posology and method of administration

Adults and children over 8 years

250–500 mg every 6 hours or 0.5–1 g every 12 hours, up to 4 g daily in severe infections. If administration on a twice-daily schedule is desirable, one-half of the total daily dose may be given every 12 hours, one hour before meals.

Children under 8 years (including infants and babies)

For younger children, infants and babies, erythromycin ethylsuccinate suspensions are normally recommended. The recommended dose for children aged 2–8 years for mild to moderate infections is 1 g daily in divided doses. The recommended dose for infants and babies for mild to moderate infections is 500 mg daily in divided doses. For severe infections, doses may be doubled.

Elderly

No special dose recommendations.

Method of administration

For oral administration only. The tablets should be swallowed whole and should not be crushed or chewed.

4.3 Contraindications

- Hypersensitivity to erythromycin, other macrolide antibiotics, or to any of the excipients listed in section 6.1.
- Concomitant use with simvastatin, tolterodine, mizolastine, amisulpride, astemizole, terfenadine, domperidone, cisapride or pimozide.
- Patients with a history of QT prolongation (congenital or documented acquired QT prolongation) or ventricular cardiac arrhythmia, including torsades de pointes.
- Patients with electrolyte disturbances (hypokalaemia, hypomagnesaemia) due to the risk of prolongation of the QT interval.
- Concomitant use with ergotamine or dihydroergotamine.

4.4 Special warnings and precautions for use

Allergic reactions

As with other macrolides, rare serious allergic reactions, including acute generalised exanthematous pustulosis (AGEP), have been reported. If an allergic reaction occurs, the drug should be discontinued and appropriate therapy should be instituted. Physicians should be aware that reappearance of the allergic symptoms may occur when symptomatic therapy is discontinued.

Hepatic impairment

Erythromycin is excreted principally by the liver, so caution should be exercised when administering the antibiotic to patients with impaired hepatic function or when concomitantly receiving potentially hepatotoxic agents. Hepatic dysfunction including increased liver enzymes and/or cholestatic hepatitis, with or without jaundice, has been infrequently reported with erythromycin.

Pseudomembranous colitis

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including macrolides, and may range in severity from mild to life-threatening. Clostridium difficile-associated diarrhoea (CDAD) has been reported with use of nearly all antibacterial agents including erythromycin, and may range in severity from mild diarrhoea to fatal colitis. CDAD must be considered in all patients who present with diarrhoea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

Cardiovascular effects — QT prolongation

Prolongation of the QT interval, reflecting effects on cardiac repolarisation imparting a risk of developing cardiac arrhythmia and torsades de pointes, have been seen in patients treated with macrolides including erythromycin. Fatalities have been reported. Erythromycin should be used with caution in patients with coronary artery disease, severe cardiac insufficiency, conduction disturbances or clinically relevant bradycardia; in patients concomitantly taking other medicinal products associated with QT prolongation; and in elderly patients who may be more susceptible to drug-associated effects on the QT interval.

Carefully consider the balance of benefits and risks before prescribing erythromycin for any patients taking hydroxychloroquine or chloroquine, because of the potential for an increased risk of cardiovascular events and cardiovascular mortality.

Congenital syphilis

There have been reports suggesting erythromycin does not reach the foetus in adequate concentrations 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.

Myasthenia gravis

There have been reports that erythromycin may aggravate the weakness of patients with myasthenia gravis.

Rhabdomyolysis

Rhabdomyolysis with or without renal impairment has been reported in seriously ill patients receiving erythromycin concomitantly with statins.

Infantile hypertrophic pyloric stenosis (IHPS)

There have been reports of infantile hypertrophic pyloric stenosis (IHPS) occurring in infants following erythromycin therapy. Epidemiological studies including meta-analyses suggest a 2–3-fold increase in the risk of IHPS following exposure to erythromycin in infancy. This risk is highest following exposure during the first 14 days of life. The risk of IHPS in the general population is 0.1–0.2%. 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.

Laboratory test interference

Erythromycin interferes with the fluorometric determination of urinary catecholamines.

4.5 Interaction with other medicinal products and other forms of interaction

Increases in serum concentrations of the following drugs metabolised by the cytochrome P450 system may occur when administered concurrently with erythromycin: acenocoumarol, alfentanil, astemizole, bromocriptine, carbamazepine, cilostazol, ciclosporin, digoxin, dihydroergotamine, disopyramide, ergotamine, hexobarbitone, methylprednisolone, midazolam, omeprazole, phenytoin, quinidine, rifabutin, sildenafil, tacrolimus, terfenadine, domperidone, theophylline, tolterodine, triazolam, valproate, vinblastine, and antifungals (fluconazole, ketoconazole, itraconazole). Appropriate monitoring should be undertaken and dosage adjusted as necessary. Particular care should be taken with medications known to prolong the QTc interval.

CYP3A4 inducers:

Drugs that induce CYP3A4 (such as rifampicin, phenytoin, carbamazepine, phenobarbital, St John's Wort) may induce the metabolism of erythromycin, leading to sub-therapeutic levels and a decreased effect. The induction decreases gradually during two weeks after discontinuation of CYP3A4 inducers. Erythromycin should not be used during and two weeks after treatment with CYP3A4 inducers.

HMG-CoA reductase inhibitors (statins):

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. Concomitant use of erythromycin with simvastatin is contraindicated.

Oral contraceptives:

Some antibiotics may in rare cases decrease the effect of contraceptive pills by interfering with the bacterial hydrolysis of steroid conjugates in the intestine, thereby decreasing reabsorption of unconjugated steroid.

Antihistamine H1 antagonists:

Care should be taken in the co-administration of erythromycin with H1 antagonists such as terfenadine, astemizole and mizolastine due to alteration of their metabolism by erythromycin. Rare cases of serious, potentially fatal cardiovascular events including cardiac arrest, torsades de pointes and other ventricular arrhythmias have been observed.

Ergotamine and dihydroergotamine:

Co-administration of erythromycin with ergotamine or dihydroergotamine has been associated with acute ergot toxicity characterised by vasospasm and ischaemia of the central nervous system, extremities and other tissues. This combination is contraindicated.

Cisapride and pimozide:

Elevated cisapride levels have been reported with concomitant erythromycin, resulting in QTc prolongation and cardiac arrhythmias including ventricular tachycardia, ventricular fibrillation and torsades de pointes. Concomitant use is contraindicated.

Theophylline:

Erythromycin use in patients receiving high doses of theophylline may be associated with an increase in serum theophylline levels and potential theophylline toxicity. If toxicity occurs, the dose of theophylline should be reduced during concomitant erythromycin therapy. There are reports suggesting that concomitant oral erythromycin may significantly decrease erythromycin serum concentrations, potentially resulting in sub-therapeutic levels.

Oral anticoagulants:

There have been reports of increased anticoagulant effects when erythromycin and oral anticoagulants (e.g. warfarin, rivaroxaban) are used concomitantly.

Triazolam, midazolam and related benzodiazepines:

Erythromycin has been reported to decrease the clearance of triazolam, midazolam, and related benzodiazepines, and may increase their pharmacological effect.

Colchicine:

Post-marketing reports of colchicine toxicity have been received with concomitant use of erythromycin and colchicine.

Verapamil:

Hypotension, bradyarrhythmias and lactic acidosis have been observed in patients receiving concurrent verapamil.

Cimetidine:

Cimetidine may inhibit the metabolism of erythromycin, leading to increased plasma concentrations.

Hydroxychloroquine and chloroquine:

Observational data have shown that co-administration of macrolide antibiotics with hydroxychloroquine or chloroquine is associated with an increased risk of cardiovascular events and cardiovascular mortality. Careful consideration of the benefit-risk balance is required before prescribing this combination.

Antibacterial agents:

An in vitro antagonism exists between erythromycin and bactericidal beta-lactam antibiotics (e.g. penicillin, cephalosporin). Erythromycin antagonises the action of clindamycin, lincomycin and chloramphenicol. The same applies for streptomycin, tetracyclines and colistin.

Zopiclone:

Erythromycin has been reported to decrease the clearance of zopiclone and may increase its pharmacodynamic effects.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is a large amount of data from observational studies on exposure to erythromycin during pregnancy (>24,000 first-trimester exposures). While most studies do not suggest an association with adverse foetal effects such as major congenital malformations, cardiovascular malformations or miscarriage, there is limited epidemiological evidence of a small increased risk of major congenital malformations, specifically cardiovascular malformations, following first-trimester exposure to erythromycin. Erythromycin should therefore only be used during pregnancy if clinically needed and the benefit of treatment is expected to outweigh any small increased risks which may exist.

Erythromycin has been reported to cross the placental barrier in humans, but foetal plasma levels are generally low.

Breast-feeding

Erythromycin is excreted in breast milk. Caution should be exercised when erythromycin is administered to a nursing mother due to reports of infantile hypertrophic pyloric stenosis in breast-fed infants. There have been reports that maternal macrolide antibiotic exposure within 7 weeks of delivery may be associated with a higher risk of infantile hypertrophic pyloric stenosis (IHPS).

Fertility

No data are available on the effect of erythromycin on human fertility.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Summary of the safety profile

The most frequent side effects of oral erythromycin preparations are gastrointestinal and are dose-related. Cardiac effects including QT prolongation and torsades de pointes have been reported and may be fatal. Hepatic dysfunction and serious skin reactions have also been reported.

Tabulated list of adverse reactions

Adverse reactions are listed by MedDRA System Organ Class. Where frequency is known, the following convention is used: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (frequency cannot be estimated from the available data).

System Organ Class	Adverse Reaction	Frequency
Blood and lymphatic system disorders	Eosinophilia	Not known
Cardiac disorders	QTc interval prolongation, torsades de pointes, palpitations, cardiac rhythm disorders including ventricular tachyarrhythmias	Not known
	Cardiac arrest, ventricular fibrillation	Not known
Ear and labyrinth disorders	Deafness, tinnitus (reversible hearing loss, primarily in patients with renal insufficiency or at high doses)	Not known

System Organ Class	Adverse Reaction	Frequency
Eye disorders	Mitochondrial optic neuropathy	Not known
Gastrointestinal disorders	Upper abdominal discomfort, nausea, vomiting, diarrhoea, anorexia	Common
	Pancreatitis, infantile hypertrophic pyloric stenosis	Not known
	Pseudomembranous colitis (rare)	Rare
General disorders	Chest pain, fever, malaise	Not known
Hepatobiliary disorders	Cholestatic hepatitis, jaundice, hepatic dysfunction, hepatomegaly, hepatic failure, hepatocellular hepatitis	Not known
Immune system disorders	Allergic reactions ranging from urticaria and mild skin eruptions to anaphylaxis	Not known
Investigations	Increased liver enzyme values	Not known
Nervous system disorders	Confusion, seizures, vertigo (transient CNS side effects; causal relationship not established)	Not known
Psychiatric disorders	Hallucinations	Not known
Renal and urinary disorders	Interstitial nephritis	Not known
Skin and subcutaneous tissue disorders	Skin eruptions, pruritus, urticaria, exanthema, angioedema, Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme	Not known
	Acute generalised exanthematous pustulosis (AGEP)	Not known
Vascular disorders	Hypotension	Not known

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose

Symptoms: hearing loss, severe nausea, vomiting and diarrhoea.

Treatment: gastric lavage and general supportive measures. There is no specific antidote for erythromycin. Management is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Macrolides. ATC Code: J01FA01.

Mechanism of action

Erythromycin exerts its antimicrobial action by binding to the 50S ribosomal subunit of susceptible microorganisms and suppressing protein synthesis. Erythromycin is usually bacteriostatic but may be bactericidal in high concentrations against highly susceptible organisms.

Spectrum of activity

Erythromycin is usually active against most strains of the following organisms both in vitro and in clinical infections:

Gram-positive bacteria: Listeria monocytogenes, Corynebacterium diphtheriae (as an adjunct to antitoxin), Staphylococci spp., Streptococci spp. (including Enterococci).

Gram-negative bacteria: Haemophilus influenzae, Neisseria meningitidis, Neisseria gonorrhoeae, Legionella pneumophila, Moraxella (Branhamella) catarrhalis, Bordetella pertussis, Campylobacter spp.

Mycoplasma: Mycoplasma pneumoniae, Ureaplasma urealyticum.

Other organisms: Treponema pallidum, Chlamydia spp., Clostridia spp., L-forms, the agents causing trachoma and lymphogranuloma venereum.

5.2 Pharmacokinetic properties

Absorption

Erythromycin stearate is absorbed from the small intestine. Peak blood levels normally occur within 1–2 hours of dosing. The elimination half-life is approximately 2 hours. Doses may be administered 2, 3 or 4 times a day.

Distribution

Erythromycin is widely distributed throughout body tissues and body fluids. It achieves high concentrations in tissues, particularly the liver, lungs and spleen. It penetrates into most body compartments.

Biotransformation

Little metabolism occurs with erythromycin stearate.

Elimination

Only about 5% of an erythromycin dose is excreted in the urine. Erythromycin is excreted principally by the liver in active form in the bile.

5.3 Preclinical safety data

No specific preclinical safety concerns have been identified beyond those reflected in other sections of this SmPC. Erythromycin has a well-established safety profile from extensive clinical use.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The following excipients are present in the film-coated tablet:

No.	Ingredient
1	Maize starch
2	Povidone (PVP K-30)
3	Isopropyl alcohol
4	Talc
5	Croscarmellose sodium
6	Colloidal anhydrous silica
7	Hydroxypropylmethylcellulose (HPMC 15 cps)
8	Titanium dioxide (E171)
9	Erythrosine (E127) (excipient with known effect)
10	Methylene chloride

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C. Protect from light and moisture. Keep out of the reach and sight of children.

6.5 Nature and contents of container

10 tablets packed in one ALU-PVC blister. 10 such blisters are packed in one carton with package insert. Pack size: 100 tablets.

6.6 Special precautions for disposal and other handling

No special requirements. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

ZAIN PHARMA LTD.
Plot No. 209/13741, Colchester Park,
Go-Down No. 1, 2, 3, Off Mombasa Road,
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P.O. Box: 100167-00101, Nairobi, Kenya.

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