1.6.1 PRESCRIBING INFORMATION (SUMMARY OF PRODUCTS CHARACTERISTICS)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

ERYKO -250 (Erythromycin Stearate Tablets BP 250mg)

1.1 Strength

250 mg

1.2 Pharmaceutical Form

Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Qualitative declaration:

Each Film Coated Tablets contains:

Erythromycin Stearate BP

Equivalent to Erythromycin ……250 mg

2.2 Quantitative declaration:

Qualitative declaration:

Each Film Coated Tablets contains:

Erythromycin Stearate BP

Equivalent to Erythromycin ……250 mg

Quantitative declaration:

Sr. No	Ingredient	Ref.	Qty/tab (mg)	Qty/tab (%)	Function
01.	Erythromycin Stearate	BP	410.00@	85.77%	Active
02.	Maize Starch	BP	26.00	5.40%	Diluent & Binder
03.	Polyvinyl Pyrollidone (PVP K-30)	BP	7.00	1.46%	Binder
04.	Colloidal Anhydrous Silica	BP	3.00	0.62%	Glidant
05.	Croscarmellose Sodium	BP	16.00	3.34%	Disintegrant
06.	Hydroxypropyl Methylcellulose (Methocel E-5 Premium)	USP/NF	5.80	1.21%	Film forming agent
07.	Polyethylene Glycol 6000	USP/NF	1.50	0.31%	Plasticizer
08.	Purified Talc	BP	7.90	1.65%	Glidant
09.	Titanium Dioxide	BP	0.80	0.16%	Opacifier
10.	Colour : Erythrosine Lake	IHS	0.30	0.06%	Colourant
11.	Purified Water*	BP	--	--	Process Solvent
		Total	**478**	100	

@- the actual quantity of active depend upon the Assay & Water content.
BP - British pharmacopoeia
USP /NF– United States Pharmacopoeia/ National Formulary
IHS- In-house specification

* - process solvent does not contribute to weight of tablet

2.3 Salts and hydrates

Pure form present No Salt or hydrate form.

2.4 Esters and pro-drugs

Not applicable

2.5 Oral Powders for solution or suspension

Not applicable

2.6 Parenterals excluding powders for reconstitution

Not applicable

2.7 Powders for reconstitution prior to parenteral administration

Not applicable

2.8 Concentrates

Not applicable

2.9 Transdermal patches

Not applicable

2.10 Multidose solid or semi-solid products

Not applicable

2.11 Biological medicinal products

Not applicable

3. Pharmaceutical form

Description:

Pink Coloured, film coated circular biconvex tablets without any visible defects.

4 Clinical Particulars

4.1 Therapeutic indications

ERYKO Tablets are indicated in treatment of susceptible infections in patients with,

- Oral infections
- Respiratory tract infections (including legionnaires disease)
- Whooping cough
- Campylobacter enteritis
- Syphilis
- Non-gonococcal urethritis
- Skin infections
- Chronic prostatitis
- Prophylaxis of diphtheria
- Group A streptococcal infection, acne vulgaris and rosacea.

4.2 Posology and Method of Administration

Posology:

Adults and CHILD over 8 years

250-500mg every 6 hours or 0.5-1g every 12 hours upto 4g daily in divided doses in severe infections

- Early syphilis: 500mg, 4 times daily for 14 days
- Uncomplicated genital chlamydia, non-gonococcal urethritis: 500mg twice daily for 14 days
- Lyme disease: 500mg 4 times daily for 14-21 days
- Renal impairment: Max. 1.5g daily

Route of administration: Oral

4.3 Method of Administration

Eryko 250 should be swallowed with glass of water.

4.4 Contraindications

Eryko 250 is contraindicated in patients with known hypersensitivity to erythromycin or any other macrolides. Use is contraindicated in acute porphyria.

4.5 Special warnings and precautions for use

Erythromycin is excreted principally by the liver, so caution should be exercised in administering the antibiotic to patients with impaired hepatic function or concomitantly receiving potentially hepatotoxic agents.

ERYKO Tablets are not recommended for use in Neonates.

Children below 8 years of age. Pseudomembranous colitis has been reported with nearly all antibacterial agents, including macrolides, and may range in severity from mild to life-threatening. Treatment with antibacterial agents alters the normal flora of the colon, which may lead to overgrowth of C. difficile or other non-susceptible micro-organisms. There have been reports that erythromycin may aggravate the weakness of patients with myasthenia gravis.

Pediatric population

ERYKO- 250 Tablets are recommended for children above 2 years of age.

The safety and efficacy of ERYKO- 250 Tablets in children 2 years and below have not yet been established.

4.6 Interactions with other medicinal products and other forms of interactions

Erythromycin increases plasma concentration of alfentanil, disopyramide, dronedarone. Concurrent administration with erythromycin should be avoided due to increased risk of toxicity and side-effects. Erythromycin enhances plasma concentration of carbamazepine, loratadine, rupatadine, darifenacin, clozapine, quetiapine, buspirone, zopiclone, digoxin, cilostazole, everolimus, eplerenone, eletriptan, pravastatin, galantamine, sildenafil, sirolimus, tacrolimus, tadalafil, theophylline, vardenafil. Concomitant use should be avoided.

Erythromycin inhibits metabolism of mizolastine, midazolam, felodipine, ciclosporin, corticosteroids, avoid concomitant use. Plasma concentration of erythromycin increased by cimetidine and ritonavir. Concomitant use should be avoided Avoid use of Erythromycin with tolterodine, droperidol, amisulpride, pimozide, lercanidipine, colchicine, nilotinib, docetaxel, vinblastine, bromocriptine, cabergoline, ergotamine, methysergide, ivabradine, atorvastatin, simvastatin. Erythromycin possibly reduces anti-platelet effect of clopidogrel, increases toxicity of arsenic trioxide, reduces contraceptive effect of oestrogens and enhances anticoagulant effect of coumarins. Erythromycin reduces plasma concentration of zafirlukast, rosuvastatin while plasma concentration of erythromycin are possibly increased by ritonavir. Dose regimens should be revised or monitored in case of concomitant use.

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4.6 Pregnancy and Lactation

Erythromycin is reported not to be harmful in pregnant and nursing mothers, caution should be exercised when erythromycin is administered to a nursing and pregnant mothers.

4.7 Effects on ability to drive and use machine

Adverse effects on the ability to drive or operate machine have not been observed.

4.8 Undesirable effects

Common: Nausea, vomiting, diarrhea and abdominal discomfort.

Less common: Hepatotoxicity (including cholestatic jaundice) and rash.

Rare or Very Rare: Pancreatitis, antibiotic associated colitis, QT interval prolongation, arrhythmias, hearing loss (reversible), tinnitus, Stevens-Johnson syndrome, myasthenia like syndrome and toxic epidermal necrolysis.

4.9 Overdose and antidote

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

Treatment: gastric lavage, general supportive measures.

5.0 Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:

Antibacterial, Macrolides

ATC Code: D02184

Erythromycin exerts its antimicrobial action by binding to the 50S ribosomal sub-unit of susceptible microorganisms and suppresses protein synthesis. Erythromycin may be either bacteriostatic or bactericidal, depending upon its serum concentration and the susceptibility of the micro-organism.

The in-vitro antibacterial spectrum of pathogens usually sensitive to Erythromycin is as follows (In-vitro sensitivity does not necessarily imply in vivo efficacy):

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

Peak plasma concentrations were achieved in 2 hours of oral dosing. The elimination half-life is approximately 5 hours. After absorption, erythromycin diffuses readily into most body fluids, including middle ear and prostatic fluid, but the highest concentrations are in the liver, bile and spleen.

Erythromycin is highly plasma protein bound (70 to 90 %), with more than 90% of the drug metabolised in the liver and excreted in the bile. After oral administration, 2 to 5% is excreted renally. Erythromycin crosses the placenta, but concentrations in foetal plasma are low.

5.3 Pre-clinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to those already included in other sections. Non-clinical data reveal no special hazards for humans based on conventional studies of safety, pharmacology, repeat–dose toxicity or genotoxicity.

6.0 Pharmaceutical Particulars

6.1 List of Excipients

Sr. No.	Ingredients	Specifications
1.	Erythromycin Stearate	BP
2.	Maize Starch	BP
3.	Polyvinyl Pyrollidone (PVP K-30)	BP
4.	Colloidal Anhydrous Silica	BP
5.	Croscarmellose Sodium	BP
6.	Hydroxypropyl Methylcellulose (Methocel E-5 Premium)	USP/NF
7.	Polyethylene Glycol 6000	USP/NF
8.	Purified Talc	BP
9.	Titanium Dioxide	BP
10.	Colour : Erythrosine Lake	IHS
11.	Purified Water	BP

6.2 Incompatibilities:

None

6.3 Shelf life

Proposed shelf life: 36 Months (3 years)

6.4 Special precautions for storage:

Store below 30°C in a dry place. Protect from light and moisture.

6.5 Nature and contents of container

Alu/Pvc Blister Pack of 10x10 Tablets OR

HDPE Jar pack of 1000 Tablets

6.6 Special precautions for disposal and other handling

None.

7. Marketing authorization holder.

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