SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Brand Name: ERYTHROKANT- 500
Generic Name: Erythromycin Stearate Tablets BP 500mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:
Erythromycin Stearate BP
Equivalent to Erythromycin……500 mg
Excipients……q.s.
Colour: Titanium Dioxide

3. PHARMACEUTICAL FORM

Oral, Solid Dosage Form-Tablets

White colored, oval, biconvex film coated tablets with break line on one side and plain on 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 great variety of clinical infections such as:

1. Upper Respiratory Tract infections: tonsillitis, peritonsillar abscess, pharyngitis, laryngitis, sinusitis, secondary infections in influenza and common colds

2. Lower Respiratory Tract infections: tracheitis, acute and chronic bronchitis, pneumonia (lobar pneumonia, bronchopneumonia, primary atypical pneumonia), bronchiectasis, Legionnaire's disease

3. Ear infection: otitis media and otitis externa, mastoiditis

4. Oral infections: gingivitis, Vincent's angina

5. Eye infections: blepharitis

6. Skin and soft tissue infections: boils and carbuncles, paronychia, abscesses, pustular acne, impetigo, cellulitis, erysipelas.

7. Gastrointestinal infections: cholecystitis, staphylococcal enterocolitis

8. Prophylaxis: pre- and post- operative trauma, burns, rheumatic fever

9. Other infections: osteomyelitis, urethritis, gonorrhoea, syphilis, lymphogranuloma venereum, diphtheria, prostatitis, scarlet fever.

4.2 Posology and method of administration:

In streptococcal infections, erythromycin stearate should be administered at therapeutic dosage for at least 10 days. For continuous prophylaxis of streptococcal infections or rheumatic fever recurrences in persons with a history of rheumatic heart disease, the dose is 250 mg twice a day. When used prior to surgery to prevent endocarditis (see hemolytic streptococcus) a recommended schedule for adults is 1 g before the procedure and 500 mg every 6 hours for 8 doses after the procedure.
Treatment of primary syphilis:2 - 4 grams per day given in divided doses over a period of 10 to 15 days.
Treatment of gonorrhoea: 500 mg four times daily for 5 days.

POSOLOGY AND MODE OF ADMINISTRATION:
In order to obtain optimal blood levels, Erythromycin should be given on an empty stomach.

MODE OF ADMINSTRATION: Oral.

DOSAGE:
For Adults:
250 mg to 500mg every 6 hours depending on the severity of the infection.

For Children:
The basic recommendation ranges from 30 to 50 mg /kg/day or more. Depending on the severity of the infections; these amounts are administered in four divided dose
Erythromycin is primarily a bacteriostatic antibiotic with a broad spectrum of action, which was recommended in the treatment of a wide variety of infections caused by susceptible organisms.
It has been used in cases such as: bronchitis, gastroenteritis Campylobacter severe diphtheria, Legionnaires' disease Legionella and other infections, neonatal conjunctivitis, pertussis, pneumonia, sinusitis and in combination with neomycin.

Erythromycin can be administered in lieu of penicillin in patients allergic to penicillin with a variety of conditions including coal, prophylaxis of endocarditis, leptospirosis, otitis media (usually with a sulphonylurea such as sulfisoxazole), pharyngitis and prevention of rheumatic fever and skin infections, staphylococcus and streptococcus.

4.3 Contraindications:

Patients with impaired liver function or patients who have developed jaundice or other symptoms of liver toxicity during previous treatment with an erythromycin. Known hypersensitivity to erythromycin.

4.4 Warning and precautions for use

Erythromycin should not be given concomitantly with chloramphenicol or thiamphenicol. Erythromycin may potentiate the action of carbamazepine, cyclosporin, corticosteroids, digoxin, theophylline and warfarin, probably by inhibition of their hepatic metabolism.
Erythromycin may interfere with some diagnostic tests including measurements of urinary catecholamines, 17-hydroxycorticosteroids and 17-ketosteroids, and with the microbiological measurements of blood folate. To avoid the ototoxicity of erythromycin in patients with renal failure, it is suggested that the daily dosage should not exceed 15 g in patients with serum creatinine above 180 micromol per litre; hearing acuity should be tested before and during treatment, especially in the elderly; and erythromycin should not be given with other potentially ototoxic medicines. There have been reports of excessive prolongation of prothrombin times in patients receiving erythromycin concurrently with chronic coumarin-type anti-coagulant therapy. Such patients, particularly the elderly, may be at risk for developing bleeding due to this interaction. In patients receiving erythromycin during chronic treatment with a coumarin-type anticoagulant, prothrombin times should be monitored closely and the coumarin-type anticoagulant dosage adjusted accordingly. Development of bacterial strains resistant to erythromycin is more common during prolonged treatment of infections more difficult to eradicate.

4.5 Drug Interactions

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, cyclosporin, digoxin, dihydroergotamine, disopyramide, ergotamine, hexobarbitone, methylprednisolone, midazolam, omeprazole, phenytoin, quinidine, rifabutin, sildenafil, tacrolimus, terfenadine, theophylline, triazolam, valproate, vinblastine, and antifungals e.g fluconazole, ketoconazole and itraconazole. Drugs that induce CYP3A4 (such as rifampicin, phenytoin, carbamazepine, phenobarbital) may induce the metabolism of erythromycin. This may lead to sub-therapeutic levels of erythromycin and a decreased effect. 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 and thereby reabsorption of unconjugated steroid. Erythromycin significantly alters the metabolism of terfenadine, astemizole and pimozide when taken concomitantly. Protease inhibitors: in concomitant administration of erythromycin and protease inhibitors, an inhibition

of the decomposition of erythromycin has been observed. 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. Cimetidine may inhibit the metabolism of erythromycin which may lead to an increased plasma concentration. Erythromycin has been reported to decrease the clearance of zopiclone and thus may increase the pharmacodynamic effects of this drug.

4.6 Pregnancy & Lactation

PREGNANCY AND LACTATION:

There are no adequate and well-controlled studies in pregnant women. However, observational studies in humans have reported cardiovascular malformations after exposure to medicinal products containing erythromycin during early pregnancy. Erythromycin has been reported to cross the placental barrier in humans, but foetal plasma levels are generally low. Erythromycin is excreted in breast milk, therefore, caution should be exercised when erythromycin is administered to a nursing mother.

4.7 Effects on ability to drive and use machines:

Not known.

4.8 Adverse Effects

Blood and lymphatic system disorders:

Eosinophilia.

Cardiac disorders

QTc interval prolongation, torsades de pointes, palpitations, and cardiac rhythm disorders including ventricular tachyarrhythmias.

Gastrointestinal disorders

The most frequent side effects of oral erythromycin preparations are gastrointestinal and are dose-related. The following have been reported: upper abdominal discomfort, nausea, vomiting, diarrhoea, pancreatitis, anorexia, infantile hypertrophic pyloric stenosis. Pseudomembranous colitis has been rarely reported in association with erythromycin therapy.

General disorders and administration site conditions.

Chest pain, fever, malaise.

Hepatobiliary disorders

Cholestatic hepatitis, jaundice, hepatic disfunction, hepatomegaly, hepatic failure, hepatocellular hepatitis.

Immune system disorders

Allergic reactions ranging from urticaria and mild skin eruptions to anaphylaxis have occurred.

Investigations

Increased liver enzyme values.

Nervous system disorders: There have been isolated reports of transient central nervous system side effects including confusion, seizures and vertigo; however, a cause and effect relationship has not been established.

Psychiatric disordersHallucinations

Renal and urinary disorders

Interstitial nephritis

Skin and subcutaneous tissue disorders

Skin eruptions, prurituls, urticaria, exanthema, angioedema, Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme.

Vascular disorders

Hypotension.

4.9 Overdose

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

Treatment: gastric lavage, general supportive measures.

5.0 PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

ATC code: J01FA01

Erythromycin exerts its antimicrobial action by binding to the 50S ribosomal sub-unit of susceptible microorganisms and suppresses protein synthesis. 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.

Note: The majority of strains of Haemophilus influenzae are susceptible to the concentrations reached after ordinary doses.

5.2 Pharmacokinetic properties

Peak blood levels normally occur within one hour of dosing of erythromycin ethylsuccinate granules. The elimination half life is approximately two hours. Doses may be administered two, three or four times a day.

Erythromycin ethylsuccinate is less susceptible than erythromycin to the adverse effect of gastric acid. It is absorbed from the small intestine. It is widely distributed throughout body tissues. Little metabolism occurs and only about 5% is excreted in the urine. It is excreted principally by the liver.

6.0 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch, Purified Talc, Colloidal Anhydrous Silica, Sodium Starch Glycolate, Croscarmellose Sodium, Wincoat white WT-1003, Isopropyl Alcohol, Dichloromethane

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 months

6.4 Special precautions for storage:

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

Keep the medicine out of reach of children.

6.5 Nature and contents of container

10 tablets in a blister. Such 10 blisters in carton alongwith insert.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER:

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Dr. Annie Besant Road, Worli,

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8. NATIONAL REGISTRATION NUMBER

08441/REN/2022

9. DATE OF AUTHORISATION

10. DATE OF REVISION OF THE TEXT

21-06-2022