SUMMARY OF PRODUCT CHARACTERISTIC

1. NAME OF THE MEDICINAL PRODUCT

Generic Name: Erythromycin Stearate for oral suspension 125mg/5ml

Brand Name: ERYTHROKANT

Description:

White granular powder which on reconstitution with water up to 100 ml (or) 60 ml gives an orange suspension.(Reconstitution with water mark as per label requirement).

2. QUALITY AND QUANTITATIVE COMPOSITION

Each 5 ml (after reconstitution) suspension contains:

Erythromycin Stearate BP

equivalent to Erythromycin……. 125 mg

Excipients…….……..q.s

Colour: Sunset Yellow FCF

For complete list of excipients refer section 6.1

3. PHARMACEUTICAL FORM

Liquid, Oral-Dosage Form: Suspension

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 disease

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

4. Oral infections: gingivitis, vincents 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 enterpcolotos

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 continues 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 haemolytic 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 & mode of administration:

In order to obtain optimal blood levels, erythromycin should be given on an empty stomach.

Mode of administration: oral

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 SPECIAL WARNING AND PRECAUTION FOR USE

Erythromycin should not be given concomitantly with chloramphenicol or thiamphenicol. Erythromycin may potentiate the action of carbamazepine, cyclosporine, 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 ad 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 180micromol 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 anti-coagulant, prothrombin times should be monitored closely and coumarin-type anticoagulant dosage accordingly.

Development of bacterial strains resistant to erythromycin is more common during prolonged treatment of infections more difficult to eradicate.

4.5 INTERACTION WITH OTHER MEDICAL PRODUCTS AND OTHER FORM OF

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, cyclosporine, digoxin, dihydroergotamine, disopyramide, ergotamine, hexabarbitone, methylprednisolone, midazolam, omeprazole, phenytoin, quinidine, rifabutin, sildenafil, tacrolimus, terfenadine, theophylline, triazolam, valproate, vinblastine & antifungals e.g. fluconazole, ketoconazole and itraconazole. Drugs that induce CYP3A4 (such as rifampicin, phenytoin, carbamazepine, henobarbitol) may induce the metabolism 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 there by reabsorption of conjugated 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 concentrations. Erythromycin has been reported to decrease the clearance of zopiclone and thus may increase the pharmacodynamics effects of this drug.

4.6 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 MACHINE

Not known.

4.8 UNDESIRABLE EFFECTS

Blood & 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,.

Hepatobilary disorders:

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

Immune system disorders:

Allergic reactions ranging from urticarial 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 disorders hallucinatios, Renal and urinary disorders, Intestinal nephritis, Skin and subcutaneous tissue disorders.

Skin eruption, prurituls, urticarial, exanthema, angioederma, stevens-johnson syndrome, toxic epidermal necrolysis erythema multiforme.

Vascular disorders, Hypotension.

4.9 OVERDOSE

Symptoms of overdosage include nausea, vomiting and diarrhoea. The treatment consists of symptomatic and supportive care.

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, legionnaries 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 sulphonylurea such as sulfisoxazole), pharyngitis and prevention of rheumatic fever and skin infections, staphylococcus and streptococcus.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Erythromycin stearate is an antibiotic belonging to the macrolide group and acts by inhibition of protein synthesis of the micro organisms. It produces peak plasma levels in one to four hours, depending on the rapidity of gastric emptying. The level declines after four to six hours.

The antibiotic is concentrated in the liver and excreted in active form in the bile. About 2 - 5% of the drug is excreted in the urine, also in the active form. It diffuses readily in most body fluids, mainly in pleural and peritoneal fluids. Passage of the antibiotic across the blood brain barrier is increased in meningeal inflammation. It crosses the placental barrier but foetal plasma levels are low (5 - 20% of maternal plasma levels).

5.2 Pharmacokinetics

Peak blood levels normally occur within one hour of dosing of erythromycin ethyl succinate granules. The elimination half life is approximately two hours. 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.

5.3 Preclinical Safety Data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sucrose (Sugar Pharma Grade), Carmellose Sodium, Methyl Hydroxybenzoate, Disodium Hydrogen Ortho Phosphate, Colloidal Anhydrous Silica, Flavour Strawberry Powder, Flavour Raspberry Powder, Sodium Citrate Anhydrous, Aspartame, Color Sunset Yellow FCF Supra, Xanthan gum.

6.2 Incompatibilities

Not Applicable.

6.3 Shelf Life

36 months from the date of Manufacture.

6.4 Special Precaution for Storage

Store below 30°C, in a dry place.

Protect from light.

Keep all medicines away from children.

6.5 Nature and Contents of Container

60 ml/100 ml bottle

7. APPLICANT/MANUFACTURER

Manufactured by:

S Kant
HEALTHCARE Ltd.

1802-1805, G.I.D.C., Phase III,

Vapi - 396 195. Gujarat, INDIA.