MECURE INDUSTRIES PLC

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Me Cure's Erythromycin Tablets BP 500 mg

2. Qualitative and quantitative composition

Each tablet contains 500 mg Erythromycin BP

3. Pharmaceutical form

Film-coated tablets

White oblong shaped film coated tablet with break-line on one side and other side is plain

4. Clinical particulars

4.1 Therapeutic indications

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

Antibiotic, highly effective in the treatment of a great variety of infections.

- 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, legionnaires 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.
- Gastro-intestinal infections: staphylococcal enterocolitis, cholecytis

- Other infections: gonorrhoea, syphilis, urethritis, osteomyelitis, lymphogranuloma venereum, diphtheria, prostatis, scarlet fever.
- Prophylaxis: pre- and post-operative, burns, trauma, rheumatic fever.

Note: Erythromycin has also proved to be of value in endocarditis and septicaemia, but in these conditions initial administration of erythromycin lactobionate by the intravenous route is advisable.

4.2 Posology and method of administration

Posology

Oral

The tablets should be swallowed whole and should not be crushed or chewed.

ADULT and CHILD 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 in adults or children, one-half of the total daily dose may be given every 12 hours, one hour before meals.

Elderly:

No special dosage recommendation.

4.3 Contraindications

Known hypersensitivity to erythromycin. Concomitant use with astemizole, terfenadine, cisapride or pimozide.

Erythromycin is contraindicated with ergotamine and dihydroergotamine.

4.4 Special warnings and precautions for use

Erythromycin is excreted principally in the liver, so caution should be exercised in administering the antibiotic to patients with impaired hepatic function or 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.

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.

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

Erythromycin interferes with the fluorometric determination of urinary catecholamines.

As with other broad spectrum antibiotics, pseudomembranous colitis has been reported rarely with erythromycin.

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

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of Erythromycin with terfenadine or astemizole is likely to result in an enhanced risk of cardiotoxicity with these drugs. The concomitant use of Erythromycin with either astemizole or terfenadine is therefore contraindicated.

The metabolism of terfenadine and astemizole is significantly altered when either are taken concomitantly with erythromycin. Rare cases of serious cardiovascular events have been observed, including torsades de pointes, other ventricular arrhythmias and cardiac arrest. Death has been reported with the terfenadine / erythromycin combination.

Elevated cisapride levels have been reported in patients receiving erythromycin and cisapride concomitantly. This may result in QT prolongation and cardiac arrhythmias including ventricular tachycardia, ventricular fibrillation and Torsades de pointes.

Similar effects have been observed with concomitant administration of pimozide and clarithromycin, another macrolide antibiotic.

Concurrent use of erythromycin and ergotamine or dihydroergotamine has been associated in some patients with acute ergot toxicity characterised by the rapid development of severe peripheral vasospasm and dysaesthesia.

Increases in serum concentrations of the following drugs metabolised by the cytochrome P450 system may occur when administered concurrently with erythromycin: alfentanil, astemizole, bromocriptine, carbamazepine, cyclosporin, digoxin, dihydroergotamine, disopyramide, ergotamine, hexobarbitone, midazolam, phenytoin, quinidine, tacrolimus, terfenadine, theophylline, triazolam, valproate, and warfarin. Appropriate monitoring should be undertaken and dosage should be adjusted as necessary.

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

When oral erythromycin is given concurrently with theophylline, there is also a significant decrease in erythromycin serum concentrations. The decrease could result in subtherapeutic concentrations of erythromycin.

4.6 Pregnancy and lactation

There is no evidence of hazard from erythromycin in human pregnancy. It has been in widespread use for a number of years without apparent ill consequence. Animal studies have shown no hazard.

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

No effect.

4.8 Undesirable effects

Occasional side effects such as nausea, abdominal discomfort, vomiting and diarrhoea may be experienced. Reversible hearing loss associated with doses of erythromycin usually greater than 4g per day has been reported.

As with other broad spectrum antibiotics, pseudomembranous colitis has been reported rarely with erythromycin.

Allergic reactions are rare and mild, although anaphylaxis has occurred. Skin reactions ranging from mild eruptions to erythema multiforme, Stevens-Johnson Syndrome and toxic epidermal necrolysis have rarely been reported.

There are no reports implicating erythromycin products with abnormal tooth development, and only rare reports of damage to the blood, kidneys or central nervous system.

Cardiac arrhythmias have been very rarely reported in patients receiving erythromycin therapy. There have been isolated reports of chest pain, dizziness and palpitations, however, a cause and effect relationship has not been established.

Symptoms of hepatitis, hepatic dysfunction and/or abnormal liver function test results may occur.

The rare possibility of super infection caused by overgrowth of non-susceptible bacteria or fungi should be considered during prolonged or repeated therapy, especially when other antibacterial agents are simultaneously employed.

4.9 Overdose

Symptoms are mainly confined to hearing loss, severe nausea, vomiting and diarrhoea. Treatment is gastric lavage and general supportive measures.

5. Pharmacological properties

5.1 Pharmacodynamic properties

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 1 hour of dosing of erythromycin ethylsuccinate granules. The elimination half-life is approximately 2 hours. Doses may be administered 2, 3 or 4 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.

5.3 Preclinical safety data

Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

The tablet contains:

Micro crystalline Cellulose

Talcum

Magnesium stearate.

Starch

Cross Carmellose sodium

Aerosol

Sodium Starch Glycolate

Sodium Lauryl Sulphate

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store in a cool dry place at temperature below 30°C. Store in the original packaging.

6.5 Nature and contents of container

Blister pack containing 10 tablets.

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing authorization holder

Me Cure Industries Limited

Plot 6 Block H, Debo Industries Compound,

Oshodi Industrial Scheme,

Oshodi,

Lagos,

Nigeria.

8.0 NAFDAC Registration Number: A11-0263