**ERYTHROX®**
**(Erythromycin BP)Tablets or Suspension**

**Qualitative and quantitative com position:**
Each 5 ml of the reconstituted suspension contains: Erythromycin (as Stearate) BP 125 mg
Each 5 ml of the reconstituted suspension of Erythrox DS contains Erythromycin (as Stearate) BP 250mg
Each Tablet contains Erythromycin (as Stearate) BP 250 mg/500mg

**List of excipients:**
Sorbitol, Glycerin, Sodium Citrate, Sodium CMC, Propylene glycol, Disodium Edetate, sodium metabisulphite, Sodium Propyl Paraben, Pineapple Flavor liquid, tartrazine colour, Sodium saccharin ,Bronopol, Citric Acid, Purified and Water.

**Pharmacology:**
Erythromycin is a macrolide antibiotic which acts by inhibition of protein synthesis by binding to the 50 S ribosomal subunits of susceptible micro-organisms. It does not affect nucleic acid synthesis. Erythromycin has been shown to be active against most strains of the following organisms in clinical infections:
**Gram-positive organisms***: Corynebacterium diptheriae, Listeria monocytogenes, Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus pyogenes.*
**Gram-negative organisms***: Bordetella pertussis, Legionella pneumophila, Neisseria gonorrhoeae.*
**Other Micro-organisms***: Chlamydia trachomatis Entamoeba histolytica, Mycoplasma pneumoniae, Treponema pallidum.*
**Pharmacokinetics**
***Absorption***: Erythromycin is completely and rapidly absorbed via gastrointestinal tract after oral administration with a peak serum levels occurring in 15 – 45 minutes with a bio-availability of 96% ± 10%. Erythromycin diffuses readily into most body fluids. Only low concentrations are achieved in the spinal fluid though this increases significantly in meningitis. In normal hepatic function, erythromycin is concentrated in the liver. Erythromycin is metabolized by hepatic microsomal enzymes. Erythromycin is principally excreted in bile, though about 5% is excreted in urine as inactive metabolites .Erythromycin crosses the placental barrier and is also excreted in breast milk.
**Therapeutic indications:**
Erythromycin is indicated for the treatment of the following infections when caused by susceptible microorganisms: Mild to moderate upper respiratory tract infections, Mild to moderate lower respiratory tract infections, Whooping cough (pertussis), Listeriosis, diphtheria, skin and skin structure infections, Acute pelvic inflammatory disease, Syphilis as an alternative to penicillins, Conjunctivitis of newborns, pneumonia of infancy, urogenital infections during pregnancy, uncomplicated urethral, endocervical or rectal infections caused by Chlamydia trachomatis, prophylaxis for initial attacks of rheumatic fever.
**Dosage and Administration:**
To be taken orally.
Adults and children over age 8 years: 250 - 500 mg every 6 hours or 0.5 – 1g every 12 hours.
Children 2– 8 years: 250 mg every 6 hours.
1 month to 2 years: 125mg every 6 hours.
Neonate: 12.5mg/kg every 6 hours.
Doses doubled for severe infections.
**Contraindications:**
Known hypersensitivity to erythromycin.
Erythromycin is contraindicated in patients taking simvastatin, tolterodine, mizolastine, amisulpride, astemizole, terfenadine, and cisapride or pimozide. Erythromycin is contraindicated with ergotamine and dihydroergotamine.
**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. 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 receiving erythromycin concomitantly with lovastatin.
**Pregnancy and lactation**
Erythromycin 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.
**Effects on ability to drive and use machines:** None known
**Side 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. 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

**Overdose:**
Symptoms: hearing loss, severe nausea, vomiting and diarrhoea. Treatment involves gastric lavage, general supportive measures.
**Shelf life:** 3 years
**Storage condition:**
Erythrox® should be stored below 30°C, in a dry place, protected from direct sunlight.
Keep out of reach of children.
**Legal category:** Prescription only medicine (POM)
**Nature and contents of container:**
Dry powder for Suspension: In 60ml and100 ml bottles
Tablets: Blister pack of 10 x 10's in unit boxes, Bulk pack of 500 or 1000 tablets in HDPE jars.
**Manufactured by**:

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| DAWA | **DAWA Limited,**<br>**Plot No. 7879/8, Baba Dogo Road, Ruaraka**<br>**P. O. Box 16633 – 00620, Nairobi, Kenya.** |

Ref: Lf /DL/ Erythrox /03 Date of issue: July 2018