**Prescribing information (Summary of Product Characteristics)**

## 1. Name of the medicinal product

Duraxyl® Suspension

## 2. Qualitative and quantitative composition

Each 5ml when reconstituted contains: Cefadroxil BP equivalent to Cefadroxil anhydrous125mg

## 3. Pharmaceutical form

Dry powder for Oral Suspension
Off white granular powder that forms a yellow sweet suspension with pleasant-Tutti fruity aroma on reconstitution with water. Packed in 60ml and 100mL HDPE bottle contained in a unit box with literature insert.

## 4. Clinical particulars

### 4.1 Therapeutic indication

Generally, Cefadroxil is useful for urinary tract infections which do not respond to other drugs or which occur in pregnancy, respiratory tract infections, sinusitis, skin and soft-tissue infections caused by Cefadroxil sensitive organisms

### 4.2 Dosage

Patients over 40 kg: 0.5 -1gm twice daily.
For skin, soft tissue and simple urinary tract infection, 1gm daily
Children over 6 years: 500mg twice daily
Children below 6 years: 30mg/kg/day in equally divided doses every 12 hours.
**Notes and dosages**:
Treatment of group A beta-hemolytic streptococcal pharyngitis and tonsillitis should be carried out for at least 10 days.
Doses should be reduced in patients with impaired renal function.

### 4.3 Contraindications

**Duraxyl®** preparations are contraindicated in; Hypersensitivity to Cefadroxil or other cephalosporins; Previous immediate and/or severe hypersensitivity reaction to penicillin or to any other beta-lactam medicinal products; Porphyria.

### 4.4 Interactions

The renal excretion of Cefadroxil is delayed by probenecid resulting in increased plasma concentrations.

### 4.5 Warnings

**Duraxyl®** like all antibiotics should be administered continuously to any patient who has demonstrated some form of hypersensitivity reactions to drugs.
If an allergic reaction occurs due to treatment with **Duraxyl®,** administration of the medicament should be stopped and corrective measures instituted.
Pseudomembraneous colitis which has been reported with all antibacterial drugs may occur. If this happens, treatment with **Duraxyl®** should be withdrawn and appropriate corrective management procedures for the colitis undertaken.

**4.6 Precautions**

Prolonged use of **Duraxyl®,** like any other antibiotic, may result in superinfection. If superinfection occurs during **Duraxyl®** therapy appropriate measures should be taken.

Positive direct Coomb's tests have been reported during treatment with cephalosporins.

Clinical experience with **Duraxyl®** with patients having moderate or severe renal impairment is limited, therefore, careful clinical experience and laboratory studies should be made in such cases.

**Duraxyl®**, just like other antibiotics should be prescribed with caution in patients with a history of gastrointestinal disease, particularly colitis.

Studies have not been performed to determine potential of **Duraxyl®** for carcinogenicity, mutagenicity or impairment of fertility.

**Duraxyl®** should be used during pregnancy only if clearly needed.

**4.7 Adverse reactions**

Gastrointestinal: Onset of Pseudomembraneous colitis symptoms may occur during or after antibiotic treatment.

Dyspepsia, nausea and vomiting have been reported rarely.

Diarrhoea, has also occurred.

Hypersensitivity reactions; Allergies in the form of rash, ucticaria, angioedema and pruritis have been observed. These reactions usually subside upon discontinuation of Duraxyl. Anaphylaxis has also been reported.

Other reactions: genital pruritus, genital moniliasis, vaginitis, moderate transient neutropenia, fever hepatic dysfunction including cholestasis and elevated serum transaminase have been reported.

Agranulocytosis, thrombocytopenia, idiosyncratic hepatic failure, erythema multiforme, Stevens - Johnson syndrome, serum sickness and arthralgia have been rarely reported.

The following adverse reactions and altered laboratory tests have been reported for cephalosporins and may as such be observed with Duraxyl; Toxic epidermal necrolysis, abdominal pain, superinfection, renal dysfunction, toxic nephropathy, aplastic anaemia, haemolytic anaemia, haemorrhage, prolonged prothrombin time, positive coombs' test, increased BUN, increased creatinine, elevated alkaline phosphatase, elevated; AST, ALT, LDH and biliiubin, eosinophilia, pancytopenia, neutropenia.

Cephalosporins may trigger seizures particularly in patients with renal impairment on high doses.

**4.8 Treatment of Overdosage**

This may be necessary particularly in children when amounts greater than
250mg/kg have been ingested in which case gastric emptying should be induced. Absorbed Cefadroxil may be removed by haemodialysis.

**5. Pharmacological properties**

**5.1 Pharmacodynamics properties**

Cefadroxil is rapidly absorbed following oral administration of 500mg and 1gm, peak plasma concentrations of about 16 and 30 g per ·ml respectively are obtained after 1.5to 2 hours.

Administration with food does not appear to affect the absorption of Cefadroxil. About 20% of Cefadroxil in the circulation is bound to plasma proteins. The plasma half-life of Cefadroxil is about 1.5 hours and is prolonged in patients with impaired renal function.

Sustained plasma concentrations of Cefadroxil is obtained and remain measurable 12 hours following administration.

Cefadroxil is widely distributed in body tissues and fluids. It crosses the placenta and appears in breast milk.

More than 90% of a dose of Cefadroxil may tie excreted unchanged in the urine within 24 hours by glomeruli filtration and tubular secretion. Peak urine concentrations are approximately 1.8mg/ml during the period following a single 500mg oral dose.

Increase in dosage generally produce a proportionate increase in Cefadroxil urinary concentration.

A 1gm dose of Cefadroxil will maintain a urine concentration well above the MIC of susceptible urinary pathogens for 20 to 22 hours.

**5.2 Pharmacokinetic properties**

**Duraxyl®** preparations contain Cefadroxil, a semi-synthetic, water soluble, acid-stable first generation cephalosporin antibiotic that is orally active.

Cefadroxil .exerts its bactericidal activity on growing and dividing bacteria by inhibiting bacterial cell-wall synthesis.

Cefadroxil inhibits the final cross-linking stage of peptidoglycan production. It does this by binding to and inactivating transpeptidases and penicillin-binding proteins on the inner surface of bacteria cell membrane leading to lysis. Additional inactivation of endogenous inhibitors of bacterial autolysins by Cefadroxil promotes further lysis of the bacteria.

Generally Cefadroxil is most active against Gram-positive cocci and has moderate activity against some Gram-negative bacilli. Gram-positive anaerobes are also sensitive.

Cefadroxil has been shown to be active in vitro and in clinical infections against the following organisms.

- Beta-haemolytic streptococci
- Moraxella (Branhamella) catarrhalis
- Staphylococci, including penicillinase- producing strains
- Klebsiella species
- Streptococcus (Diplococcus) pneumoniae
- Salmonella species
- Escherichia coli
- Shigella species
- Proteus mirabilis
- Neisseria species
- Haemophilus influenzae

Cefadroxil is ineffective against methicillin-resistant staphylococci, penicillin resistant Streptococcus pneumoniae, enterococci, Listeria monocytogenes, Enterobacter, indole-positive Proteus or Serratia species, Bacteriodes fragilis, Pseudomonas species, Acinetobacter calcoaceticus, Mycobacteria, Mycoplasma and Fungi.

**5.3 Preclinical safety data**

No additional data of relevance to prescriber.

**6. Pharmaceutical particulars**

**6.1 List of Excipients**

Aspartame
White Refined Sugar
Sodium Benzoate
Sodium CMC
Xanthan Gum
Colloidal Silicon Dioxide
Tutti Fruity Powder Flavour
Tartrazine Yellow Soluble Colour
Magnesium Stearate

**6.2 Incompatibilities**

None known

**6.3 Shelf life**

24 Months

**6.4 Special precautions for storage**

Store in a dry place below 30ºC
Protect from light.
Keep all medicine out of reach of children.
Replace cap securely after use.

**6.5 Nature and contents of container**
Off white granular powder that forms a yellow sweet suspension with pleasant-Tutti fruity aroma on reconstitution with water. Packed in 60ml and 100mL HDPE bottle contained in a unit box with literature insert.

**6.6 Special precautions for disposal and other handling**
No special requirements

**7. Marketing authorization holder**
**Marketing Authorization Holder:**
**Company Name:** LABORATORY & ALLIED LTD
**Address:** Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa road, P.O. Box 42875 GPO 00100, Nairobi,
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