APPROVED PACKAGE INSERT

SCHEDULING STATUS:

S4

PROPRIETARY NAME (and dosage form):

TETRALYSAL® 300 mg Capsules

COMPOSITION:

TETRALYSAL® 300 mg: Each hard gelatin capsule contains Lymecycline equivalent to 300 mg Tetracycline Base.

Excipients: Magnesium stearate; silica, colloidal hydrated.

Gelatin capsule is composed of Gelatin, Erythrosin colour, indigo carmine colour, titanium dioxide.

PHARMACOLOGICAL CLASSIFICATION:

A 20.1.1 – Broad and medium spectrum antibiotics.

PHARMACOLOGICAL ACTION:

Pharmacodynamics

Lymecycline is a bacteriostatic antibiotic which inhibits bacterial growth by binding to 30S ribosomal sub unit with consequent misreading of information for protein synthesis. It is effective *in-vitro* against the following gram-positive and gram-negative organisms (*in*-vitro activity does not necessarily imply *in-vivo* efficacy):

Vibrio cholerae, Ureaplasma urealyticum, Mycoplasma pneumoniae, Chlamydia trachomatis, Chlamydia psittaci, Borrelia recurrentis, Calyminatobacterium granulomatis, Borrelia burgdorferi, penicillin sensitive *Neisseria gonorrhoea* and *Rickettsiae*.

Lymecycline is also effective against the following organisms *in-vitro*:

Haemophilus ducreyi, Actinomyces israelii, Francisella tularensis, Treponema pertenue.

Resistant pathogens

Many of the following strains are resistant: *Staphylococci*, *Enterococci, Proteus vulgaris*, Fungi and Yeasts (except Actinomyces), *Pseudomonas aeruginosa* (all strains), *E. coli, Shigella, Streptococcus*.

Pharmacokinetics

Lymecycline is incompletely absorbed from the intestinal tract. Effective blood levels are reached in about two to four hours after oral administration and are maintained with the recommended dosages.

Lymecycline is distributed into pleural and peritoneal fluid, saliva, semen and prostatic fluid. It passes the placental barrier readily (amniotic fluid) and is also present in milk of lactating patients. It is concentrated by the liver and excreted into the bile. Enterohepatic circulation is an important step in the metabolic pathway. Excretion in the urine is by glomerular filtration.

INDICATIONS:

Infections caused by susceptible strains of pathogens:

Upper and lower respiratory tract infections:

Sinusitis, pharyngitis, Mycoplasma pneumoniae, psittacosis and chronic bronchitis.

Genito-urinary tract infections:

Non-specific urethritis (only if the strain is sensitive), lymphogranuloma venereum, chancroid and granuloma inguinale, gonococcal salpingitis, epididymitis, acute epididymo-orchitis, endocervical infections, syphilis and gonorrhoea (in cases of penicillin allergy).

Soft tissue:

Acne

Opthalmic infections:

Trachoma and inclusion conjunctivitis.

Intestinal infections:

Cholera, Whipple's disease and tropical sprue.

Miscellaneous infections:

Rickettsial infections, brucellosis, tularemia, actinomycosis, Lyme disease, yaws, relapsing fever, leptospirosis during the early infective phase.

CONTRAINDICATIONS:

Hypersensitivity to tetracyclines or to any of the excipients.

In patients with impaired renal function.

Should not be given to children younger than 12 years of age as permanent discolouration of the child's teeth may occur.

Should not be given to patients with systemic lupus erythematosus.

WARNINGS AND SPECIAL PRECAUTIONS:

Use in children under the age of 12 years is not recommended.

Use with care in patients with liver function impairment.

Frail or elderly patients are susceptible to hepatotoxic medicines and antianabolic effects of tetracyclines.

Do not use concomitantly with hepatotoxic medicines.

Symptoms of Myasthenia gravis may be aggravated.

Photosensitivity may occur (see “SIDE-EFFECTS”).

Raised intracranial pressure may occur particularly in infants and especially if Vitamin A or other retinoids are given concomitantly.

The use of expired tetracyclines may lead to a Fanconi-type syndrome which is characterised by polyuria and polydipsia with nausea, vomiting, proteinuria, glucosuria, acidosis, aminoaciduria, hypophosphatemia and hypocalcaemia.

Effects on ability to drive and use machines

TETRALYSAL® 300 mg is not known to affect the ability to drive or use machines

INTERACTIONS:

Preparations containing sodium bicarbonate, iron, aluminium, calcium, or magnesium, may decrease the absorption of lymecycline. Patients should therefore not receive antacid therapy or milk concomitantly.

Doses of anticoagulants may need to be reduced if given concomitantly.

Penicillin should not be given concomitantly with tetracyclines as antagonism may occur.

Tetracyclines may diminish the effectiveness of oral contraceptives.

Serious nephrotoxicity may follow the concomitant use with methoxyflurane

PREGNANCY AND LACTATION:

Tetralysal® 300 mg should not be used by pregnant or breastfeeding women.

Pregnancy

Lymecycline crosses the placenta and is deposited in foetal bones and teeth.

Pregnant women are particularly susceptible to severe tetracycline-induced liver damage.

Lactation

Tetracyclines readily cross the placental barrier and are distributed into milk.

DOSAGE AND DIRECTIONS FOR USE:

The usual dose for ADULTS is 300 mg every 12 hours (depending on the severity of the infection).

The capsules should be taken either one hour before meals or two hours after meals with adequate liquid to avoid lodging of capsules in the distal oesophagus as this may result in local corrosive irritation and ulceration.

The maximum dose should not exceed 3 g daily for adults and 50 mg/kg body mass per day for children.

SIDE-EFFECTS:

Gastro-intestinal side-effects include nausea, vomiting, diarrhoea, glossitis, dysphagia related to eosophagitis and enterocolitis.

Symptoms resulting from the overgrowth of non-susceptible organisms:

Overgrowth of Candida albicans in the mouth causes soreness, redness and thrush which may extend into the trachea and bronchi; overgrowth of C. albicans in the bowel results in pruritis ani and vulvovaginitis and there may be overgrowth of resistant coliform organisms, such as Pseudomonas spp. and Proteus spp., causing diarrhoea. Colitis due to Clostridium difficile may occur. Super-infection due to resistant staphylococci may cause fulminating enteritis.

Blood abnormalities:

Haemolytic anaemia, eosinophilia, neutropenia, thrombocytopenia.

Allergic (hypersensitivity) reactions:

Allergic reactions to lymecycline and its analogues have been reported. Cross-sensitisation is common. Symptoms include urticaria, maculopapular rashes, exfoliative dermatitis, exacerbation of systemic lupus erythematosus, pericarditis, Henoch-Schönlein purpura (anaphylactoid purpura), angioneurotic oedema and anaphylaxis.

Photosensitivity of the skin and nails; oncholysis and nail discolouration may occur.

Increased severity of uraemia and hepatotoxicity in patients with renal disease given high doses

Vitamin deficiencies may result during prolonged administration.

A Jarisch-Herxheimer-like reaction has been reported in patients with relapsing fever treated with tetracycline.

In the elderly a negative nitrogen balance may be induced.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See “Side-effects”.

If adverse reactions or idiosyncrasy occur, discontinue medication. Treatment is symptomatic and supportive.

IDENTIFICATION:

A yellow and red gelatin capsule containing a granular yellow powder.

PRESENTATION:

Blisterpacks containing 28 capsules packed in a carton.

STORAGE INSTRUCTIONS:

Store in a cool dry place at or below 25 ºC.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

E/20.1.1/67

NAME AND BUSINESS ADDRESS OF THE APPLICANT HOLDER OF THE CERTIFICATE OF REGISTRATION:

Galderma Laboratories South Africa (Pty) Ltd

17 Muswell Road South

Bryanston

2021

DATE OF PUBLICATION OF THIS THE PACKAGE INSERT:

March 1995