LOFECTION LB

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

abbreviated prescribing information for LOFECTION LB (Doxycycline and Lactic Acid Bacillus Capsules) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: ***Doxycycline:*** The main mechanism of action of doxycycline is on protein synthesis. Doxycycline passes directly through the lipid bilayer of the bacterial cell wall and an energy dependent active transport system pumps the drug through the inner cytoplasmic membrane. Once inside the cell doxycycline inhibits protein synthesis by binding to 30S ribosomes and prevents the addition of amino acids to the growing peptide chain. Doxycycline will impair protein synthesis in mammalian cells at very high concentrations but these cells lack the active transport system found in bacteria. Doxycycline is clinically effective in the treatment of a variety of infections caused by a wide range of gram-negative and gram-positive bacteria, as well as certain other micro- organisms. ***Lactic Acid Bacillus:*** The mechanism of action is presumed to be a result of improving gastrointestinal ecology made possible by replenishing the quantity of desirable obligate microorganisms and antagonizing pathogenic microbes.

INDICATION: It is indicated for adult patients prone to intrabdominal bacterial infection & Antibiotic associated diarrhoea

DOSAGE AND ADMINISTRATION: Doxycycline (Cpasule): 100mg and Lactic Acid Bacillus: 5 billion spores, Should be taken as directed by Physician**.**

CONTRAINDICATION: ***Doxycycline:*** Pregnancy: Doxycycline is contraindicated in pregnancy. It appears that the risks associated with the use of tetracyclines during pregnancy are predominantly due to effects on teeth and skeletal development. Nursing mothers: Tetracyclines are excreted into milk and are therefore contraindicated in nursing mothers. Sucrose intolerance: Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrose-isomaltase insufficiency should not take doxycycline. ***Lactic Acid Bacillus:*** This medicine is not recommended for use in patients with a known allergy to lactic acid bacillus or any other inactive ingredients present along with it.

WARNINGS & PRECAUTIONS: ***Doxycycline:*** *In p*aediatric population the use of drugs of the tetracycline class during tooth development (last half of pregnancy; infancy and childhood to the age of 8 years) may cause permanent discolouration of the teeth (yellow-grey-brown). This adverse reaction is more common during long-term use of the drugs but has been observed following repeated short-term courses. Enamel hypoplasia has also been reported. *Photosensitivity*: Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines, including doxycycline. *Use in patients with impaired hepatic function*: Doxycycline should be administered with caution to patients with hepatic impairment or those receiving potentially hepatotoxic drugs. Abnormal hepatic function has been reported rarely and has been caused by both the oral and parenteral administration of tetracyclines, including doxycycline. *Use in patients with renal impairment*: Excretion of doxycycline by the kidney is about 40%/72 hours in individuals with normal renal function. This percentage excretion may fall to a range as low as 1-5%/72 hours in individuals with severe renal insufficiency (creatinine clearance below 10ml/min). Studies have shown no significant difference in the serum half-life of doxycycline in individuals with normal and severely impaired renal function. *Serious skin reactions*: such as exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in patients receiving doxycycline. *Microbiological overgrowth*: The use of antibiotics may occasionally result in overgrowth of non-susceptible organisms including Candida. If a resistant organism appears, the antibiotic should be discontinued and appropriate therapy instituted. *Pseudomembranous colitis* has been reported with nearly all antibacterial agents, including doxycycline. *Clostridium difficile* associated diarrhoea (CDAD) has been reported with use of nearly all antibiotics, including doxycycline, and has ranged in severity from mild diarrhoea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C difficile. Benign intracranial hypertension*: Bulging fontanelles in infants have been reported in individuals receiving tetracyclines. Benign intracranial hypertension (pseudotumor cerebri) has

been associated with the use of tetracyclines including doxycycline. Benign intracranial hypertension (pseudotumor cerebri) is usually transient, however cases of permanent visual loss secondary to benign intracranial hypertension (pseudotumor cerebri) have been reported with tetracyclines including doxycycline. Also There have been reports of porphyria, *Venereal disease, Beta-haemolytic streptococci infections, Myasthenia gravis*, systemic lupus erythematosus (SLE), *Jarisch-Herxheimer reaction* who receving doxycycline. ***Lactic Acid Bacillus:*** If your doctor has prescribed this medicine along with antibiotics, then it should be taken between two scheduled doses of the antibiotics. Discuss therapy with your doctor to avoid/minimize the interaction between antibiotics and this medicine.

DRUG INTERACTIONS: ***Doxycycline:*** The absorption of doxycycline may be impaired by concurrently administered antacids containing aluminium, calcium, magnesium or other drugs containing these cations; oral zinc, iron salts or bismuth preparations. Dosages should be maximally separated. Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving doxycycline in conjunction with penicillin. There have been reports of prolonged prothrombin time in patients taking warfarin and doxycycline. Tetracyclines depress plasma prothrombin activity and reduced doses of concomitant anticoagulants may be necessary. The serum half-life of doxycycline may be shortened when patients are concurrently receiving barbiturates, carbamazepine or phenytoin. An increase in the daily dosage of Doxycycline should be considered. Alcohol may decrease the half-life of doxycycline. A few cases of pregnancy or breakthrough bleeding have been attributed to the concurrent use of tetracycline antibiotics with oral contraceptives. Doxycycline may increase the plasma concentration of ciclosporin. Co-administration should only be undertaken with appropriate monitoring. The concurrent use of tetracyclines and methoxyflurane has been reported to result in fatal renal toxicity. Concomitant use of isotretinoin or other systemic retinoids and doxycycline should be avoided. Each of these agents used alone has been associated with benign intracranial hypertension (pseudotumor cerebri). Laboratory test interactions: False elevations of urinary catecholamine levels may occur due to interference with the fluorescence test. Drugs that induce hepatic enzymes such as rifampicin may accelerate the decomposition of doxycycline, thereby decreasing its half-life. Sub-therapeutic doxycycline concentrations may result. Monitoring concurrent use is advised and an increase in doxycycline dose may be required. Ergotamine; There is an increased risk of ergotism when doxycycline is co-administered with ergotamine. Methotrexate; Doxycycline increases the risk of methotrexate toxicity; prescribe with caution to patients on methotrexate. Quinapril contains magnesium carbonate and may interfere with the absorption of doxycycline. ***Lactic Acid Bacillus:*** The common drug interactions have been noticed with the following drugs: Alcohol (mild), Antibiotics (mild) and Immunosuppressants (mild).

ADVERSE REACTIONS: ***Doxycycline:*** **Infections and infestations**: Vaginal infection, Candida Infection, pseudomembranous colitis, Clostridium difficile colitis. **Blood and lymphatic system disorders**: Haemolytic anaemia, neutropenia, thrombocytopenia, eosinophilia **Immune system disorders**: Hypersensitivity (including anaphylactic shock, anaphylactic reaction, anaphylactoid reaction, exacerbation of systemic lupus erythematosus, serum sickness) Jarisch-Herxheimer reaction· **Congenital, familial and genetic disorders**: Porphyria **Endocrine disorders**: Brown-black microscopic discolouration of thyroid glands **Metabolism and nutrition disorders**: decreased appetite. **Nervous system disorders**: Headache, benign intracranial hypertension (pseudotumor cerebri)[*], fontanelle bulging **Psychiatric Disorders**: Anxiety **Ear and labyrinth Disorders**: Tinnitus. **Vascular disorders**: hypotension, Flushing. **Gastrointestinal disorders**: Nausea/vomiting, Dyspepsia (Heartburn/gastritis), Pancreatitis, oesophageal ulcer, oesophagitis, enterocolitis, inflammatory lesions (with monilial overgrowth) in the anogenital region, dysphagia, abdominal pain, diarrhoea, glossitis, stomatitis, tooth discolouration. **Hepatobiliary disorders**: Hepatic failure, hepatitis, hepatotoxicity, jaundice, hepatic function abnormal. **Skin and subcutaneous tissue disorders**: Photosensitivity reaction, rash including maculopapular and erythematous rashes, Henoch- Schonlein purpura, Urticaria, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), angioedema, Toxic epidermal necrolysis, Stevens- Johnson syndrome, Erythema multiforme, Dermatitis exfoliative, photoonycholysis, skin hyperpigmentation. **Musculoskeletal, connective tissue and bone disorders:** Arthralgia, myalgia **Renal and urinary disorders**: Blood urea increased. **Cardiac Disorders**: Pericarditis, Tachycardia. **Respiratory, thoracic and mediastinal disorders**: Dyspnoea. **General disorders**

and administration site conditions: Peripheral oedema. ***Lactic Acid Bacillus:*** Acute toxicity (less common) Nausea (common) Rashes (common) Bloating (common) Abdominal pain (less common).

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

IN/ LOFECTION LB 100mg, 5 Billion Spores /APR-2022/01/ABPI
(Additional information is available on request)