

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

LOFECTION LB

1. Generic Name

Doxycycline and Lactic Acid Bacillus Capsules

2. Qualitative and quantitative composition

Each Hard Gelatin Capsule Contains

Doxycycline Hydrochloride I.P.

Equivalent To Doxycycline.....100 mg

Lactic Acid Bacillus.....5 Billion Spores

Approved Colours Used In Empty Capsule Shells

The Excipients Used Are Microcrystalline Cellulose, Dibasic Calcium Phosphate Anhydrous, PVPK-30, Sodium Starch Glycolate, Sodium Lauryl Sulfate, Aerosil, Purified Talc, Iso Propyl Alcohol, Magnesium Stearate, EHG Caps “2” Black/Orange.

3. Dosage form and strength

Dosage form: Capsule

Strength: Doxycycline : 100mg and Lactic Acid Bacillus: 5 billion spores

4. Clinical particulars

4.1 Therapeutic indication

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

4.2 Posology and method of administration

Posology

Keep the medicine out of reach of children.

Capsule should be swallowed whole & not to be chewed, opened or crushed.

Doxycycline

The capsules should be swallowed with plenty of fluid in either the resting or standing position and well before going to bed for the night to reduce the likelihood of oesophageal irritation and ulceration.

If gastric irritation occurs, it is recommended that Doxycycline Capsules be given with food or milk. Studies indicate that the absorption of doxycycline is not notably influenced by simultaneous ingestion of food or milk.

Adults and children aged 12 years to less than 18 years

The usual dosage of Doxycycline for the treatment of acute infections in adults *and children aged 12 years to less than 18 years* is 200mg on the first day (as a single dose or in divided doses with a twelve hour interval) followed by a maintenance dose of 100mg/day. In the management of more severe infections (particularly chronic infections of the urinary tract), 200mg daily should be given throughout the treatment period.

Exceeding the recommended dosage may result in an increased incidence of side effects. Therapy should be continued for at least 24 to 48 hours after the symptoms and fever have subsided.

When used in streptococcal infections, therapy should be continued for 10 days to prevent the development of rheumatic fever or glomerulonephritis.

Dosage recommendations in specific infections:

Acne vulgaris

50mg daily with food or fluid for 6 to 12 weeks.

Sexually transmitted diseases

100mg twice daily for 7 days is recommended in the following infections: uncomplicated gonococcal infections (except anorectal infections in men); uncomplicated urethral, endocervical or rectal infection caused by *Chlamydia trachomatis*; non-gonococcal urethritis caused by *Ureaplasma urealyticum*.

Acute epididymo-orchitis caused by *Chlamydia trachomatis* or *Neisseria gonorrhoea*

100mg twice daily for 10 days.

Primary and secondary syphilis: 300mg a day in divided doses for at least 10 days.

Louse and tick-borne relapsing fevers

A single dose of 100mg or 200mg according to severity.

Treatment of chloroquine-resistant falciparum malaria

200mg daily for at least 7 days. Due to the potential severity of the infection, a rapid-acting schizonticide such as quinine should always be given in conjunction with Doxycycline; quinine dosage recommendations vary in different areas.

Prophylaxis of malaria

100mg daily in adults and children over the age of 12 years. Prophylaxis can begin 1-2 days before travel to malarial areas. It should be continued daily during travel in the malarial areas and for 4 weeks after the traveller leaves the malarial area. For current advice on geographical resistance patterns and appropriate chemoprophylaxis, current guidelines or the Malaria Reference Laboratory should be consulted, details of which can be found in the British National Formulary (BNF).

For the prevention of scrub typhus

200mg as a single dose.

For the prevention of travellers' diarrhoea in adults

200mg on the first day of travel (administered as a single dose or as 100mg every 12 hours) followed by 100mg daily throughout the stay in the area. Data on the use of the drug prophylactically are not available beyond 21 days.

For the prevention of leptospirosis

200mg once each week throughout the stay in the area and 200mg at the completion of the trip. Data on the use of the drug prophylactically are not available beyond 21 days.

Children aged 8 years to less than 12 years.

The use of doxycycline for the treatment of acute infections in children aged 8 years to less than 12 years should be carefully justified in situations where other drugs are not available, are not likely to be effective or are contraindicated.

In such circumstance, the doses for the treatment of acute infections are:

For children 45 kg or less- Initial dose: 4.4 mg/kg (in single or 2 divided doses) with maintenance dose: 2.2 mg/kg (in single or 2 divided doses). In the management of more severe infections, up to 4.4 mg/kg should be given throughout treatment.

For children, over 45 kg - Dose administered for adults should be used.

Children aged from birth to less than 8 years.

Doxycycline should not be used in children aged younger than 8 years due to the risk of teeth discolouration. (Section 4.4 and 4.8)

Paediatric population: Not recommended.

Elderly patients

Doxycycline may be prescribed in the usual dose with no special precautions. No dosage adjustment is necessary in the presence of renal impairment.

Renal impairment: Studies to date have indicated that administration of doxycycline at the usual recommended doses does not lead to excessive accumulation of the antibiotic in patients with renal impairment.

The anti-anabolic action of the tetracyclines may cause an increase in blood urea. Studies to date indicate that this does not occur with the use of doxycycline in patients with impaired renal function.

Haemodialysis does not alter the serum half-life of doxycycline.

Lactic Acid Bacillus

Nutritional Information per serving (per capsule) (approx.)		
Energy	1.15	Kcal
Protein	0.02	g
Total Carbohydrate	0.268	g
Sugar	0.064	g
Starch	0.204	g

- Probiotic food
- Recommended Usage: As directed by the Healthcare Professional.
- Not for medicinal use

4.3 Contraindications

Doxycycline

- Hypersensitivity to the active substance, any of the tetracyclines or to any of the excipients listed in section 6.1
- *Pregnancy:* Doxycycline is contraindicated in pregnancy (. 4.6). It appears that the risks associated with the use of tetracyclines during pregnancy are predominantly due to effects on teeth and skeletal development (. 4.4 regarding use during tooth development).

- *Nursing mothers:* Tetracyclines are excreted into milk and are therefore contraindicated in nursing mothers (. 4.4 regarding use during tooth development).
- *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.

4.4 Special warnings and precautions for use

Doxycycline

Paediatric 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. Use doxycycline in paediatric patients aged younger than 8 years only when the potential benefits are expected to outweigh the risks in severe or life-threatening conditions (e.g. Rocky Mountain spotted fever), particularly only when there are no adequate alternative therapies.

Although the risk of permanent teeth staining is rare in children aged 8 years to less than 12 years, the use of doxycycline should be carefully justified in situations where other drugs are not available, are not likely to be effective or are contraindicated.

Photosensitivity

Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines, including doxycycline. Patients likely to be exposed to direct sunlight or ultraviolet light should be advised that this reaction can occur with tetracycline drugs and treatment should be discontinued at the first evidence of skin erythema. Photoonycholysis has also been reported in patients receiving 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.

Haemodialysis does not alter the serum half-life of doxycycline. The anti-anabolic action of the tetracyclines may cause an increase in blood urea. Studies to date indicate that this anti-anabolic effect does not occur with the use of Doxycycline in patients with impaired renal function.

Serious skin reactions

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 (. 4.8). If serious skin reactions occur, doxycycline should be discontinued immediately and appropriate therapy should be instituted.

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, and has ranged in severity from mild to life-threatening. It is important to consider this diagnosis in patients who present with diarrhoea subsequent to the administration of antibacterial agents.

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*. *C difficile* produces toxins A and B, which contribute to development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD should be considered in all patients who present with diarrhoea after antibiotic treatment. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

Oesophagitis

Instances of oesophagitis and oesophageal ulcerations have been reported in patients receiving capsule and tablet forms of drugs in the tetracycline class, including doxycycline. Most of these patients took medications immediately before going to bed or with inadequate amounts of fluid.

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. If visual disturbance occurs during treatment, prompt ophthalmologic evaluation is warranted. Since intracranial pressure can remain elevated for weeks after drug cessation patients should be monitored until they stabilize. Concomitant use of isotretinoin or other systemic retinoids and doxycycline should be avoided because isotretinoin is also known to cause benign intracranial hypertension (pseudotumor cerebri). (. 4.5)

Porphyria

There have been rare reports of porphyria in patients receiving tetracyclines .

Venereal disease

When treating venereal disease, where co-existent syphilis is suspected, proper diagnostic procedures, including dark-field examinations, should be utilised. In such cases monthly serological tests should be performed for at least four months.

Beta-haemolytic streptococci infections

Infections due to Group a beta-haemolytic streptococci should be treated for at least 10 days.

Myasthenia gravis

Due to a potential for weak neuromuscular blockade, care should be taken in administering tetracyclines to patients with myasthenia gravis.

Systemic lupus erythematosus

Tetracyclines can cause exacerbation of systemic lupus erythematosus (SLE).

Jarisch-Herxheimer reaction

Some patients with spirochete infections may experience a Jarisch-Herxheimer reaction shortly after doxycycline treatment is started. Patients should be reassured that this is a usually self-limiting consequence of antibiotic treatment of spirochete infections.

Methoxyflurane

Caution is advised in administering tetracyclines with methoxyflurane (. 4.5).

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.

4.5 Drugs 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)
- Immunosuppressants (mild)

4.6 Use in Special Populations (Such as Pregnant Women, Lactating Women, Paediatric Patients, Geriatric Patients Etc.)

Doxycycline

- Hypersensitivity to the active substance, any of the tetracyclines or to any of the excipients listed.
- 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 (regarding use during tooth development).
- Nursing mothers: Tetracyclines are excreted into milk and are therefore contraindicated in nursing mothers (regarding use during tooth development).
- Sucrose intolerance: Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrose-isomaltase insufficiency should not take doxycycline.

Lactic Acid Bacillus

Pregnancy

This medicine is considered safe for use by a pregnant woman. However, Patients are advised to consult your doctor before taking this medicine.

Breast-feeding

This medicine is considered safe for use by a breastfeeding woman. However, Patients are advised to consult your doctor before taking this medicine.

4.7 Effects on ability to drive and use machines

Visual disturbances such as blurring of vision may occur during treatment with doxycycline and in such cases; patients must refrain from driving or operating machinery.

4.8 Undesirable effects

Doxycycline

The following adverse reactions have been observed in patients receiving tetracyclines, including doxycycline.

System Organ Class	Common ≥1/100 to <1/10	Uncommon ≥1/1000 to <1/100	Rare ≥1/10,000 to <1/1000	Not known Cannot be estimated from the available data.
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 ^b (. 4.4)	
Congenital, familial and genetic disorders			Porphyria	
Endocrine disorders			Brown-black microscopic discolouration of thyroid glands	
Metabolism and			decreased appetite	

nutrition disorders				
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 ^a
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 ^c	
Musculoskeletal,			Arthralgia, myalgia	

connective tissue and bone disorders				
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			

* Symptoms included blurring of vision, scotomata and diplopia. Permanent visual loss has been reported.

A Reversible and superficial discolouration of permanent teeth has been reported with the use of doxycycline but frequency cannot be estimated from available data.

B in the setting of spirochete infections treated with doxycycline.

C with chronic use of doxycycline.

Lactic Acid Bacillus

Acute toxicity (less common)

Nausea (common)

Rashes (common)

Bloating (common)

Abdominal pain (less common)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:

http://www.torrentpharma.com/index.php/site/info/adverse_event_reporting.

4.9 Overdose

Doxycycline

Acute overdosage with antibiotics is rare. In the event of overdosage gastric lavage plus appropriate supportive treatment is indicated.

Dialysis does not alter serum half-life and thus would not be of benefit in treating cases of overdosage.

Lactic Acid Bacillus

Overdose may lead to increased chances of side effects.

5. Pharmacological properties

5.1 Mechanism of Action

Doxycycline

Pharmacotherapeutic group: tetracyclines, ATC code: J01AA02

Doxycycline is primarily a bacteriostatic antibiotic.

Mechanism of action

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 microorganisms.

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.

5.2 Pharmacodynamic 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 microorganisms.

Lactic Acid Bacillus

Despite the transient nature of this organism in the digestive tract, the changes that lactic acid bacillus produces cause a shift in the environment in support of a complex gastrointestinal flora.

Two isomeric forms of lactic acid can be produced by lactic acid-producing bacteria dextrorotatory (D (-)) lactic acid and laevorotatory (L (+)) lactic acid. L (+) lactic acid is completely metabolized in the body; however, D (-) lactic acid is not completely metabolized, resulting in a degree of metabolic acidosis. *Lactobacillus sporogenes*

produces only L (+) lactic acid. *L. sporogenes* is assumed to produce bacteriocins and short-chain fatty acids. As the organism grows, it assimilates and incorporates cholesterol into its cellular structure. *L. sporogenes* possesses significant beta-galactosidase (lactase) activity in vitro.

5.3 Pharmacokinetic properties

Doxycycline

Absorption

Doxycycline is almost completely absorbed and is not subject to presystemic metabolism, the mean bioavailability being approximately 93%.

Absorption is rapid (effective concentrations are attained as from the first hour), and the peak serum concentration occurs after 2 to 4 hours.

Almost all of the product is absorbed in the upper part of the digestive tract. Absorption is not modified by administration with meals, and milk has little effect.

Distribution

Tissue distribution is good and Doxycycline has a strong affinity for renal and lung tissue. The volume of distribution for doxycycline ranges from 0.9-1.8 l/kg.

In adults, an oral dose of 200 mg results in;

- A peak serum concentration of more than 3 µg/ml
- A residual concentration of more than 1 µg/ml after 24 hours
- A serum half-life of 16 to 22 hours.
- Protein binding varying between 82 and 93% (labile binding) intra- and extracellular diffusion is good.

With usual dosages, effective concentrations are found in the ovaries, uterine tubes, uterus, placenta, testicles, prostate, bladder, kidneys, lung tissue, skin, muscles, lymph glands, sinus secretions, maxillary sinus, nasal polyps, tonsils, liver, hepatic and gallbladder bile, gallbladder, stomach, appendix, intestine, omentum, saliva and gingival fluid. Doxycycline is transferred into breast milk.

Only small amounts are diffused into the cerebrospinal fluid.

Biotransformation

No significant metabolism occurs.

Elimination

Doxycycline is cleared intact by renal and biliary mechanisms

The antibiotic is concentrated in the bile. About 40% of the administered dose is eliminated in 3 days in active form in the urine and about 32% in the faeces.

Urinary concentrations are roughly 10 times higher than plasma concentrations at the same time. In the presence of impaired renal function, urinary elimination decreases, faecal elimination increases and the half-life remains unchanged. The half-life is not affected by haemodialysis.

Lactic Acid Bacillus

Subsequent to oral administration, LOFECTION LB passes through the stomach in its spore form and upon arrival in the duodenum, germinates and multiplies rapidly. Estimates suggest that the average duration of time between oral dosing and germination is 4 hours. After germination, LOFECTION LB metabolically active in the intestines, producing lactic acid. L sporogenesis considered semi-resident, indicating that it takes up only a temporary residence in the human intestines. Spores of LOFECTION LB are excreted slowly via the faeces for approximately 7 days after discontinuation of administration.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

Doxycycline

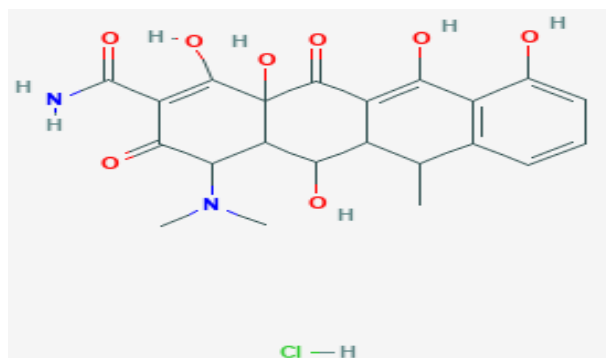
Not Applicable

Lactic Acid Bacillus

Not Available

7. Description

Doxycycline is 4-(dimethylamino)-1,5,10,11,12a-pentahydroxy-6-methyl-3,12-dioxo-4a,5,5a,6-tetrahydro-4H-tetracene-2-carboxamide; hydrochloride having molecular weight of 480.9 and empirical formula of $C_{22}H_{25}ClN_2O_8$ and the chemical structure is:



Lactic acid bacillus are inactivated bacteria that are good for the gut. They prevent the growth of the other pathogenic bacteria that cause diarrhoea or other bacterial infections. Thus, it helps in treating bacterial infections.

Doxycycline and Lactic Acid Bacillus Capsules are Black colour cap & orange colour body “2” each hard gelatin capsule shell filled with yellow powder. The excipients used are Microcrystalline Cellulose, Dibasic Calcium Phosphate anhydrous, PVPK-30, Sodium Starch Glycolate, Sodium Lauryl Sulfate, Aerosil, Purified Talc, Magnesium Stearate, EHG Caps “2” Black/Orange.

8. Pharmaceutical particulars

8.1 Incompatibilities

Not applicable

8.2 Shelf-life

Do not use later than date of expiry.

8.3 Packaging information

LOFECTION LB is available in blister strip of 10 capsules.

8.4 Storage and handing instructions.

Store in a cool, dry place below 25°C. Protected from light and moisture.

9. Patient Counselling Information.

Package leaflet: Information for the user

LOFECTION LB

Doxycycline and Lactic Acid Bacillus Capsules

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. . 9.4.

What is in this leaflet?

9.1. What Lactic LOFECTION LB is and what it is used for

9.2. What you need to know before you use LOFECTION LB 9.3.How to Take LOFECTION LB

9.3 Possible side effects

9.4 How to store LOFECTION LB

9.5 Contents of the pack and other information

9.1 What LOFECTION LB is and what it is used for

LOFECTION LB contains Doxycycline and Lactic Acid Bacillus. It is indicated for adult patients prone to intrabdominal bacterial infection & Antibiotic associated diarrhoea.

9.2 What you need to know before you use LOFECTION LB

This medicine is not recommended for use in patients with a known allergy to Doxycycline and Lactic Acid Bacillus or any other inactive ingredients present along with it.

9.3 How to Take LOFECTION LB

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Your doctor will tell you how to take the medicine each day and when to take them.
- Read the label on the carton to remind you what the doctor said.
- Try to take your capsule at the same time each day.

9.4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Doxycycline

The following adverse reactions have been observed in patients receiving tetracyclines, including doxycycline.

System Organ Class	Common ≥1/100 to <1/10	Uncommon ≥1/1000 to <1/100	Rare ≥1/10,000 to <1/1000	Not known Cannot be estimated from the available data.
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 ^b (. 4.4)	
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 ^a
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 ^c	
Musculoskeletal, connective tissue and bone disorders			Arthralgia, myalgia	
Renal and urinary disorders			Blood urea increased	
Cardiac	Pericarditis,			

Disorders	Tachycardia			
Respiratory, thoracic and mediastinal disorders	Dyspnoea			
General disorders and administration site conditions	Peripheral oedema			

* Symptoms included blurring of vision, scotomata and diplopia. Permanent visual loss has been reported.

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B in the setting of spirochete infections treated with doxycycline.

C with chronic use of doxycycline.

Lactic Acid Bacillus

Acute toxicity (less common)

Nausea (common)

Rashes (common)

Bloating (common)

Abdominal pain (less common)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:

http://www.torrentpharma.com/index.php/site/info/adverse_event_reporting.

9.5 How to store LOFECTION LB

Store in a cool, dry place below 25°C. Protected from light and moisture.

9.6 Contents of the pack and other information

The active ingredient is Doxycycline and Lactic acid bacillus

The Excipients Used Are Microcrystalline Cellulose, Dibasic Calcium Phosphate Anhydrous, PVPK-30, Sodium Starch Glycolate, Sodium Lauryl Sulfate, Aerosil, Purified Talc, Iso Propyl Alcohol, Magnesium Stearate, EHG Caps “2” Black/Orange.

LOFECTION LB is available in blister strip of 10 capsules.

10. Details of manufacturer

Manufactured by:

Theon Pharmaceuticals Ltd.

Vill. Saini Majra, Teh. Nalagarh, Distt. Solan (H.P.) – 174101

11. Details of permission or licence number with date

Mfg Lic No MNB/06/409 issued on 07.04.2021

12. Date of revision

Not applicable

MARKETED BY



TORRENT PHARMACEUTICALS LTD.

IN/ LOFECTION LB 100mg, 5 Billion Spores /APR-2022/01/PI