

Enterolife[®] Aqua

Suspension

1. Generic Names

Bacillus clausii

2. Qualitative and Quantitative Composition

Each 5ml of Enterolife contains

Bacillus clausii 2 million spores

3. Dosage form and strength

Oral suspension containing 2 million spores of *Bacillus clausii*.

4. Clinical particulars

4.1 Therapeutic indication

Enterolife Aqua Suspension is indicated for:

- Treatment of infective diarrhoea
- Treatment of antibiotic associated diarrhoea
- Adjunct therapy in recurrent respiratory tract infection and allergic rhinitis.

4.2 Posology and method of administration

As directed by physician.

4.3 Contraindication

Enterolife is contraindicated in patients with hypersensitivity to the active ingredient or any of the excipients.

4.4 Special warnings and precautions for use

During antibiotic therapy, Enterolife should be administered in the interval between 1 dose of antibiotic and the next.

4.5 Drug interactions

There are no known interactions subsequent to the concomitant use of other drugs.
Incompatibilities: There is no known incompatibility.

4.6 Use in special population

- Pediatric: Highly efficacious and safe.

- Geriatric: Safety and effectiveness of Entero Aqua suspension in geriatric patients have not been established.
- Liver impairment: No data available.
- Renal failure: No data available.
- Pregnancy and lactation: Consultation with doctor is advised.

4.7 Effects on ability to drive and use machine

No data available.

4.8 Undesirable effects

No side effects have been reported, up to the present time, with the use of the drug.

4.9 Overdose

No data available.

5. Pharmacological properties

5.1 Mechanism of action

Normal gut microbiota plays an important role in the protection of the host against gastrointestinal tract diseases. During acute diarrhoea, the normal gastrointestinal microbiota is found to undergo radical changes that facilitate the overgrowth of unwanted microorganisms, including pathogenic strains. *Bacillus* strains fight off intestinal pathogens and antibiotic-associated diarrhoea by the following mechanisms:

- Antibacterial action of the substitutive-competitive type in the intestine potentiated by a bacteriolytic/bacteriostatic or immunomodulatory action
- It is thought that the spores of *Bacillus subtilis* are transformed in the intestine, thereby releasing in the immediate neighborhood enzymatic activity that helps in the lysis of other bacteria to promote the restoration of the normal endogenous flora.
- The transformation of spores of *Bacillus subtilis* actually involves a sequence of degenerative states in the spore structure accompanied by the release of components with enzymatic lytic activity.

5.2 Pharmacodynamics properties

B. clausii was found to exert immunomodulation activity by affecting cytokine pattern at nasal level in allergic children with recurrent respiratory infections.

5.3 Pharmacokinetic properties



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NA.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

NA.

7. Description

Probiotics are live microbes, which when administered in adequate amounts confer a health benefit to the host. Bacillus species which are spore forming bacteria have been used as probiotics for the last five decades. The advantage of spore forming probiotics over nonspore formers such as Lactobacillus spp. is that:

- ✓ They are heat stable and can be stored at room temperature without any loss of viability.
- ✓ Spore forming bacteria are also resistant to acidic conditions of the stomach (low pH) and hence can survive the transit to reach the intestine. As *B. clausii* is extremely stable to acidic conditions, the entire dose of ingested bacteria reach the small intestine intact.
- ✓ Experimental data suggest that both Bacillus clausii (*B. clausii*) spores and cells can adhere to the bowel wall and colonize the mucosa.

8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

24 months.

8.3 Packaging Information

Enterolife is presented in a 10 mini bottles of 5ml per pack.

8.4 Storage and handling instructions

Store at a temperature not exceeding 25°C in a dry place. Keep the medicine out of reach of children.

9. Patient Counselling Information

9.1 Adverse Reactions

Refer part 4.8

9.2 Drug Interactions

Refer part 4.5

9.3 Dosage

Refer part 4.2

9.4 Storage

Refer part 8.4

9.5 Risk Factors

Refer part 4.4

9.6 Self-monitoring information

NA

9.7 Information on when to contact a health care provider or seek emergency help

Patient is advised to be alert for the emergence or worsening of the adverse reactions and contact the prescribing physician.

9.8 Contraindications

Refer part 4.3

10. Manufactured by Unique Biotech Ltd.

11. Details of permission or license number with date

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