

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

VIZYLAC JUNIOR

1. Generic Name

Bacillus Clausii Spores Suspension

2. Qualitative and quantitative composition

Each 5 ml of oral suspension mini bottle contains:

Spores of polyantibiotic-resistant

Bacillus clausii.....2 billion

Purified water I.P.q.s.

3. Dosage form and strength Dosage

Dosage form: Oral suspension

Strength: 5 ml of oral suspension

4. Clinical particulars

4.1 Therapeutic indication

It is indicated for alteration of intestinal bacterial flora.

4.2 Posology and method of administration

Posology

As prescribe by physician.

Shake the bottle before use. To open the bottle, break by twisting and remove the top of the cap. Take the contents directly or dilute in water or other drinks (e.g. milk, beverages)

Once open, the drug should be taken within a short time to avoid contaminating the suspension.

Method of administration

Shake the bottle before use. To open the bottle, break by twisting and remove the top of the cap. Take the contents directly or dilute in water or other drinks (e.g. milk, beverages). Once open, the drug should be taken within a short time to avoid contaminating the suspension.

4.3 Contraindications

None known

4.4 Special warnings and precautions for use

Do not use if hypersensitive to the active ingredient or excipients.

During treatment with antibiotics, it is recommended that Bacillus clausii spores suspension be administered during the interval between antibiotic administrations.

It's important to know that:

The possible presence of corpuscles visible in the mini bottles of *Bacillus clausii* spores suspension is due to aggregates of *Bacillus clausii* spores and does not, therefore, indicate that the product has undergone any changes.

4.5 Drugs interactions

Interactions with other drugs have not been observed.

4.6 Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Can be used during pregnancy and lactation; it is however preferable to check with your healthcare practitioner.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

None known

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

Excessive doses of *Bacillus clausii* spores suspension do not generally cause undesired effects.

Do not exceed the recommended doses.

5. Pharmacological properties

5.1 Mechanism of Action

B. clausii strains release antimicrobial substances in the medium. The release of these antimicrobial substances was observed during stationary growth phase and coincided with sporulation. These substances were active against Gram-positive bacteria, in particular against *Staphylococcus aureus*, *Enterococcus faecium*, and *Clostridium difficile*.

5.2 Pharmacodynamic properties

B. clausii strains release antimicrobial substances in the medium. The release of these antimicrobial substances was observed during stationary growth phase and coincided with sporulation. These substances were active against Gram-positive bacteria, in particular against *Staphylococcus aureus*, *Enterococcus faecium*, and *Clostridium difficile*. The antimicrobial activity was resistant to subtilisin, proteinase K, and chymotrypsin treatment, whereas it was sensitive to pronase treatment. The evaluation of the immunomodulatory properties of probiotic *B. clausii* strains was performed in vitro on Swiss and C57 Bl/6j murine cells and it was demonstrated that these strains, in their vegetative forms, are able to induce

NOS II synthetase. *Bacillus clausii* possesses antibiotic resistance to a few antibiotics. This resistance has been shown to be chromosome encoded and not linked to transferable genetic elements. Due to its antibiotic resistance, *Bacillus clausii* can be administered in the interval between two doses of antibiotics.

5.3 Pharmacokinetic properties

Bacillus clausii spores survive transit through the human gastrointestinal tract. They can undergo germination, out growth and multiplication as vegetative forms. Administered orally, *Bacillus clausii* spores, due to their high-resistance to both chemical and physical agents, cross the barrier of the gastric juices reaching unharmed the intestinal tract where they are transformed into metabolically active vegetative cells. The microorganisms do not colonise the human intestine but have a transient presence. Spinosa et al (2000) inoculated intragastrically, two groups of mice with a single dose of 10⁹ spores. Samples were taken from intestinal sites, lymph organs and blood at 4, 24 and 72 hours after inoculation. Spores of the inoculated *Bacillus* strains were found at the intestinal sites at 4 hours. They were largely excreted in the feces as spores, with their presence decreasing exponentially over 72 hours by when they were a 10th of the total spore count. The administration of *Bacillus clausii* contributes to the recovery of the intestinal microbial flora altered during the course of microbial disorders of diverse origin.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

Not available

7. Description

Bacillus Clausii Spores Suspension are liquid suspension with slight turbidity and without odour filled in a PE mini bottle.

8. Pharmaceutical particulars

8.1 Incompatibilities

None stated

8.2 Shelf-life

Do not use later than the date of expiry.

8.3 Packaging information

Vizylac Junior is available in 5 ml mini bottles

8.4 Storage and handing instructions

Store at a temperature not exceeding 30°C. Do not freeze

9. Patient counselling information

Package leaflet: Information for the user

VIZYLAC JUNIOR

Bacillus Clausii Spores Suspension

Read all of this leaflet carefully before you start taking 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.

What is in this leaflet?

9.1. What VIZYLAC JUNIOR is and what it is used for

9.2. What you need to know before you take VIZYLAC JUNIOR

9.3. How to take VIZYLAC JUNIOR

9.4. Possible side effects

9.5. How to store VIZYLAC JUNIOR

9.6. Contents of the pack and other information

9.1 What VIZYLAC JUNIOR is and what it is used for

VIZYLAC JUNIOR contains the active substance Bacillus Clausii Spores Suspension.

VIZYLAC JUNIOR contains spores of polyantibiotic - resistant strains of Bacillus clausii (19T, 21C, 28S & 30R).

VIZYLAC JUNIOR is used for the alteration of intestinal bacterial flora.

9.2 What you need to know before you take VIZYLAC JUNIOR

Warnings and precautions

Do not take VIZYLAC JUNIOR or talk to your doctor before taking it if having hypersensitive to the active ingredient or excipients.

During treatment with antibiotics, it is recommended that Bacillus clausii spores suspension be administered during the interval between antibiotic administrations.

It's important to know that:

The possible presence of corpuscles visible in the mini bottles of Bacillus clausii spores suspension is due to aggregates of Bacillus clausii spores and does not, therefore, indicate that the product has undergone any changes.

Other medicines and VIZYLAC JUNIOR

Interactions with other drugs have not been observed.

VIZYLAC JUNIOR with food, drink and alcohol

Take the contents directly or dilute in water or other drinks (e.g. milk, beverages).

Pregnancy, breast-feeding and fertility

Can be used during pregnancy and lactation; it is however preferable to check with your healthcare practitioner.

9.3 How to take VIZYLAC JUNIOR

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Children: 1-2 mini bottles per day; Adults: 2-3 mini bottles per day. To be used only for short periods of treatment.

Method of administration: Shake the bottle before use. To open the bottle, break by twisting and remove the top of the cap. Take the contents directly or dilute in water or other drinks (e.g. milk, beverages).

Once open, the drug should be taken within a short time to avoid contaminating the suspension.

9.4 Possible side effects

None known

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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.

By reporting side effects, you can help provide more information on the safety of this medicine.

9.5 How to store VIZYLAC JUNIOR

Store at a temperature not exceeding 30°C. Do not freeze

9.6 Contents of the pack and other information

VIZYLAC JUNIOR contains Bacillus Clausii Spores Suspension.

The active substances **VIZYLAC JUNIOR** is Bacillus clausii.

Vizylac Junior is available in 5 ml mini bottles

10. Details of manufacturer

Manufactured by:

Allianz Biosciences Private Limited

R.S. NO. 55/1,2 &3, Whirlpool Raod,

Thiruvandarkoil, Mannadipet Commune,

Puducherry-605102

11. Details of permission or licence number with date

Mfg Lic No. 03 22 1031 issued on 25.02.2021

12. Date of revision

Not applicable

MARKETED BY



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IN/VIZYLAC JUNIOR/MAY-22/01/PI