Rifaboly 100 Suspension

Rifaximin 100 mg/5 mL Suspension

Category: Antibiotic Dosage Form: Oral Suspension

Description:

Rifaximin 100 mg/5 mL Suspension is an antibiotic used to treat a variety of gastrointestinal infections. It is a broadspectrum antibiotic that works by inhibiting the growth of bacteria within the gut. Unlike many antibiotics, Rifaximin is minimally absorbed into the bloodstream, allowing it to act directly in the gastrointestinal tract. This makes it particularly effective in treating travelers' diarrhea, irritable bowel syndrome (IBS) with diarrhea, and certain types of bacterial overgrowth in the intestines.

Composition (Per 5 mL):

- Rifaximin: 100 mg
- Excipients: Syrup base, preservatives, flavoring agents, stabilizers, and water for suspension.

Indications:

- 1. Traveler's Diarrhea (Non-invasive Escherichia coli):
 - Rifaximin is effective in treating diarrhea caused by non-invasive strains of Escherichia coli (E. coli), typically acquired from contaminated food or water.

- 2. Irritable Bowel Syndrome (IBS) with Diarrhea:
 - It is used to treat IBS with diarrhea, reducing symptoms like abdominal pain, bloating, and frequent loose stools.
- **3. Small Intestinal Bacterial Overgrowth** (SIBO):
 - Rifaximin is used to treat SIBO, a condition where excessive bacteria in the small intestine cause symptoms such as bloating, gas, diarrhea, and malabsorption.
- 4. Hepatic Encephalopathy (Secondary to Liver Disease):
 - It is used to reduce the recurrence of hepatic encephalopathy, a complication of liver disease that can affect brain function.
- 5. Other Gastrointestinal Infections:
 - Can be used to treat certain GI infections caused by susceptible bacteria, as directed by a healthcare provider.

Dosage and Administration:

- Traveler's Diarrhea:
 - Adults and Children ≥12 years:
 200 mg every 8 hours for 3 days.
- Irritable Bowel Syndrome with Diarrhea (IBS-D):
 - Adults: 550 mg three times a day for 14 days.
- Small Intestinal Bacterial Overgrowth (SIBO):
 - Adults: Typically, 400 mg three times a day for 7–14 days, depending on the severity and clinical response.
- Hepatic Encephalopathy:

- Adults: 550 mg twice a day to prevent recurrence of hepatic encephalopathy.
- For Children (if indicated):
 - Dosing should be based on weight and prescribed by a healthcare provider.

Note: Always follow the exact dosing schedule provided by the prescribing healthcare professional. It is important to complete the full course of treatment, even if symptoms improve before finishing the medication.

Mechanism of Action:

Rifaximin works by inhibiting bacterial RNA synthesis. It binds to the bacterial enzyme DNA-dependent RNA polymerase, preventing bacteria from producing proteins needed for their survival. This action kills the bacteria or prevents their replication, leading to the resolution of infections in the gastrointestinal tract.

Pharmacokinetics:

- Absorption:
 - Rifaximin is poorly absorbed from the gastrointestinal tract (less than 0.4% of an oral dose). Therefore, it acts primarily within the intestines, making it effective for gastrointestinal infections.
- Distribution:
 - The drug remains mostly localized in the gut, with negligible systemic exposure.
- Metabolism and Excretion:
 - It is minimally metabolized in the liver and excreted unchanged in the feces. Due to its minimal

absorption, it has a low risk of systemic side effects.

- **Contraindications:**
 - Hypersensitivity:
 - Contraindicated in patients with a known allergy to Rifaximin or any of the excipients in the suspension.
 - Severe Liver Disease:
 - Use with caution in patients with severe liver disease, especially in those with hepatic encephalopathy.

Warnings and Precautions:

- 1. Clostridium difficile-Associated Diarrhea (CDAD):
 - Rifaximin can lead to overgrowth of Clostridium difficile, a bacterium that causes severe diarrhea. If persistent diarrhea occurs, the possibility of CDAD should be considered.
- 2. Renal and Hepatic Impairment:
 - In patients with renal or hepatic impairment, dosing may need to be adjusted. Consult with a healthcare provider before use.
- **3. Pregnancy and Breastfeeding:**
 - Pregnancy: Rifaximin should be used during pregnancy only if clearly needed and prescribed by a doctor.
 - Breastfeeding: It is not known whether Rifaximin is excreted in breast milk. Use cautiously if breastfeeding, and consult a healthcare provider.

Adverse Effects:

- Common Side Effects:
 - Gastrointestinal: Nausea, abdominal discomfort, constipation, flatulence, and bloating.
 - General: Headache, fatigue, dizziness, and fever.
- Serious Side Effects (Rare):
 - Severe allergic reactions (rash, swelling, difficulty breathing), liver toxicity (rare), or Clostridium difficile-associated diarrhea.

Drug Interactions:

- Cyclosporine:
 - Concomitant use may increase the blood levels of Cyclosporine due to reduced clearance.
- Other Antibiotics:
 - Use with caution when combining Rifaximin with other antibiotics, as it may alter the gut microbiota, potentially leading to resistance or overgrowth of other microorganisms.
- Oral Contraceptives:
 - Antibiotics can reduce the effectiveness of oral contraceptives. Consider using additional contraception methods while taking Rifaximin.

Keep out of reach of children.

Key Points for Use:

- Rifaximin 100 mg/5 mL Suspension is a safe and effective treatment for a variety of gastrointestinal infections, especially for traveler's diarrhea, IBS-D, and SIBO.
- It is well-tolerated and works mainly in the gut, reducing the potential for systemic side effects.
- Ensure adherence to the prescribed dosage and treatment duration for optimal results.
- As with all antibiotics, misuse or overuse of Rifaximin can lead to antibiotic resistance, so it should only be used when prescribed by a healthcare provider.

Note: Always consult with a healthcare provider before starting treatment, particularly if you have pre-existing medical conditions or are taking other medications.

Manufactured in India for:

Cafoli Lifecare Pvt. Ltd. (An ISO 9001: 2015 Certified Co.) Plot no.: 367-FF, Industrial Area Phase-I, Panchkula-134113 TM: Trademark Applied for

Storage Instructions:

- Store the suspension at room temperature, below 30°C (86°F).
- Keep the bottle tightly closed.
- Do not freeze.
- Shake well before each use.