Lactospey[®] Sachet

For the Use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Lyophilized Saccharomyces boulardii Powder for oral suspension Lactospey® Sachet

COMPOSITION

Each 1 gm sachet contains: Lyophilized Saccharomyces boulardii 250 mg Excipients q.s. OTHER INGREDIENTS Lactose, dextrose and mannitol. Flavour: Orange Contains permitted synthetic food colour and class II preservatives added.

DESCRIPTION

Lactospev® Sachet is a probiotic which contain Saccharomyces boulardii, a strain which has been internationally acclaimed as a well-researched and unique microorganism, and has been safely used for the last 50 years. Lactospev® Sachet works by reducing the excessive secretion of water and electrolytes in gut. Saccharomyces boulardii, a friendly yeast is more robust to environmental stressors than more common bacterial live cultures, and shows strong resistance to heat, humidity and stomach acidity levels. These live cultures of Saccharomyces boulardii have been tested and shown to be especially stable and resistant.

Lactospey® Sachet supplementation is beneficial for:

- Treatment of acute infectious diarrhoea in adults and children
- Prevention and treatment of antibiotic-associated colitis and diarrhoea
- Prevention of recurrence of Clostridium difficile diseases, in addition to vancomycin/metronidazole-treatment

DOSAGE AND ADMINISTRATION

One to two sachets twice daily or as prescribed.

METHOD AND ROUTE OF ADMINISTRATION

Powder of the sachet has to be either poured in a glass of water, or mixed with foods, or in baby's feeding bottle.

CONTRAINDICATIONS

- Known hypersensitivity to any of the ingredients of the formulation
- Patients with central venous catheter
- Pregnancy and Lactation

WARNINGS

This formulation contains living cells therefore it should not be mixed with very hot (50oC) or iced or alcohol drinks or food. The treatment with Saccharomyces boulardii does not replace rehydration. The patient should be appropriately rehydrated depending upon the severity of diarrhoea, age and the state of health of the patient.

DRUG INTERACTIONS AND OTHER FORMS OF INTERACTIONS

Because of the fungal nature of this formulation it should not be administered with systemic or oral antifungal drugs.

USE IN SPECIAL POPULATION

Pregnancy and Lactation

The safety and efficacy has not been established in pregnant and lactating women.

ADVERSE REACTIONS

Very rare cases of fungemia with fever and positive Saccharomyces hemoculture for Saccharomyces have been reported in hospitalized patients with a central venous catheter, in immunocompromised patients, in patients with gastrointestinal disease or in patients treated with high dosage.

STORAGE

Store at temperatures not exceeding 25°C. Protect from light and moisture. Do not freeze. Keep out of reach of children.

PRESENTATION

10 sachets in a monocarton.



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