

### 1.3.2 PATIENT INFORMATION LEAFLET

#### SCHEDULING STATUS

**S0**

#### INTEFLORA SACHETS powder

*Saccharomyces boulardii CNCM I-745* 250 mg per sachet

**Contains sugar: Fructose 471,90 mg, lactose 32,5 mg and sorbitol 0,11 mg per sachet**

**Read all of this leaflet carefully because it contains important information for you**

INTEFLORA SACHET is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use INTEFLORA SACHET carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share INTEFLORA SACHET with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve within 2 days.

#### **What is in this leaflet**

1. What INTEFLORA SACHET is and what it is used for
2. What you need to know before you take INTEFLORA SACHET
3. How to take INTEFLORA SACHET
4. Possible side effects
5. How to store INTEFLORA SACHET
6. Contents of the pack and other information

#### **1. What INTEFLORA SACHET is and what it is used for**

INTEFLORA SACHET belongs to a group of medicines called antidiarrheal microorganisms and is used in:

- Non-specific acute diarrhoea.
- Diarrhoea associated with antibiotic therapy.

Suitable for use in infants, children, adults and the elderly.

## **2. What you need to know before you take INTEFLORA SACHET**

Diarrhoea may be a symptom of a more serious underlying disease. If diarrhoea persist for more than 2 days or there is blood in stools or fever develops consult your doctor (see section Warnings and precautions below).

### **Do not take INTEFLORA SACHET**

- If you, your child or infant are allergic to yeast or any of the ingredients as contained in INTEFLORA SACHET.
- If you consume alcohol.
- If you, your child or infant are taking or receiving any other anti-fungal (oral or parenteral route (e.g. injections)) medicines.
- If you, your child or infant have a central venous catheter.
- If you, your child or infant are severely ill and/or hospitalised due to a disease altering your immune system.

### **Warnings and precautions**

#### **Take special care with INTEFLORA SACHET**

- If you, your child or infant have diarrhoea you need to replace fluids lost.  
INTEFLORA SACHET does not substitute fluid replacement, you still need to take plenty of fluids. You, your child or infant should be rehydrated by drinking copious

amounts of salty or sweet drinks, in order to compensate for fluid losses due to diarrhoea.

- Diarrhoea may be a symptom of a more serious underlying disease. If diarrhoea persists for more than 2 days, if there is blood in your stools or if fever develops, consult your doctor.

### **Infants and children**

If in an infant or child the diarrhoea persists after 2 days of treatment, the treatment must be reviewed and the infant or child should be rehydrated. Consult your doctor about this.

### **Other medicines and INTEFLORA SACHET**

Always tell your health care provider if you are taking any other medicine (this includes all complementary or traditional medicines).

INTEFLORA SACHET must not be taken at the same time as medicines (oral or parenteral (e.g. injections) route) used to treat fungal infections.

### **INTEFLORA SACHET with food and drink**

INTEFLORA SACHET consists of live cells, therefore it must not be mixed into very hot (above 50 °C), icy or alcohol-containing drinks or foods.

Therefore INTEFLORA SACHET should not be used concomitantly with hot beverages, ice cream and alcohol.

### **Pregnancy, breastfeeding and fertility**

Safety of INTEFLORA SACHET in pregnant and breastfeeding women has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking INTEFLORA SACHET.

### **Driving and using machines**

INTEFLORA SACHET is not expected to influence your ability to drive. However, you should not drive, use machinery or perform any tasks that require concentration until you are certain that INTEFLORA SACHET does not adversely affect your ability to do so safely (see section 4).

### **INTEFLORA SACHET contains lactose monohydrate, fructose and sorbitol**

INTEFLORA SACHET contains 32,5 mg lactose, 471,90 mg fructose and 0,11 mg sorbitol per sachet.

Fructose can damage teeth.

If your doctor has told you that you (infant or child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (infant or child) take or receive this medicine.

## **3. HOW TO TAKE INTEFLORA SACHET**

Do not share medicines prescribed for you with any other person.

Always take INTEFLORA SACHET exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

- Pour the contents of the sachets in a little amount of water or sweetened beverage, mix and drink immediately.

- INTEFLORA SACHET may be taken in conjunction with antibiotics and other anti-diarrhoeal medication.

The usual dose of INTEFLORA SACHET is:

**Diarrhoea associated with antibiotic therapy**

*Adults:* Take two sachets twice a day.

*Infants and children:* Give one sachet twice a day.

**Non-specific acute diarrhoea**

*Adults:* Take one sachet twice a day.

*Infants and children:* Give one sachet twice a day.

See section INTEFLORA SACHET with food and drink.

**If you take more INTEFLORA SACHET than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

**If you forget to take INTEFLORA SACHET**

Do not take a double dose to make up for forgotten individual doses.

**4. Possible side effects**

INTEFLORA SACHET can have side effects.

Not all side effects reported for INTEFLORA SACHET are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking INTEFLORA SACHET, please consult your healthcare provider for advice.

If the following happens, stop taking INTEFLORA SACHET and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to INTEFLORA SACHET. You may need urgent medical attention or hospitalisation.

The following has been reported:

*Less frequent:*

- Presence of fungi and/or yeasts in the blood (fungemia) in patients with a central venous catheter, and in hospitalised, immunocompromised patients.
- Passing gas (flatulence).

*Frequency unknown:*

- Constipation.
- **Serious blood infection (sepsis).**

If you notice any side effect not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

**SAHPRA:** <https://www.sahpra.org.za/Publications/Index/8>

**Aspen Pharmacare:**

**E-mail:** [Drugsafety@aspenpharma.com](mailto:Drugsafety@aspenpharma.com)

**Tel:** 0800 118 088

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

## **5. How to store INTEFLORA SACHET**

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C, protect from moisture.

Store in the original package.

Do not store in bathrooms.

Do not use after the expiry date on the sachet or the outer carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## **6. Contents of the pack and other information**

### **What INTEFLORA SACHET contains**

The active substance is 250 mg of *Saccharomyces boulardii* CNCM I-745.

The other ingredients are colloidal anhydrous silica, artificial tutti frutti flavour.

Contains sugars: Fructose 471,90 mg, lactose monohydrate 32,5 mg and sorbitol 0,11 mg.

### **What INTEFLORA SACHET looks like and contents of the pack**

A very light brown powder with an odour of fruit.

INTEFLORA SACHET are packed in cartons of 10 sachets.

The product is packed in 5 twin sachets consisting of paper/aluminium foil/ polyethylene film composite.



**Holder of Certificate of Registration**

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**Access to the corresponding Professional Information**

**SAHPRA Repository of Professional Information and Patient Information Leaflets:**

**Aspen Pharmacare:**

<https://pi-pil-repository.sahpra.org.za/>

**E-mail:** [Medinfo@aspenpharma.com](mailto:Medinfo@aspenpharma.com)

**Tel:** 0800 118 088

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