1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

INTEFLORA 250 capsule

***Saccharomyces boulardii* CNCM I-745**

Contains sugar: Lactose 32,5 mg per capsule

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

INTEFLORA 250 is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use INTEFLORA 250 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share INTEFLORA 250 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 250 is and what it is used for
2. What you need to know before you take INTEFLORA 250
3. How to take INTEFLORA 250
4. Possible side effects
5. How to store INTEFLORA 250
6. Contents of the pack and other information

1. What INTEFLORA 250 is and what it is used for

INTEFLORA 250 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 250

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 250:

- If you, your child or infant are allergic to yeast or any of the other ingredients as contained in INTEFLORA 250.
- If you consume alcohol.
- If you, your child or infant are taking or receiving any other anti-fungal medicines by oral or parenteral route (e.g. injections).
- 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 250:

- If you, your child or infant have diarrhoea you need to replace fluids lost. INTEFLORA 250 does not substitute fluid replacement, you still need to take plenty of fluids. You, your child or infant should be rehydrated by drinking (or being given) 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 the diarrhoea persists after 2 days of treatment in an infant or child, the treatment must be reviewed and the infant or child should be rehydrated. Consult your doctor about this.

Other medicines and INTEFLORA 250

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

INTEFLORA 250 must not be taken at the same time as medicines (oral or parenteral (e.g. injections) route) used to treat fungal infections.

INTEFLORA 250 with food and drink

INTEFLORA 250 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 250 should not be taken concomitantly with hot beverages, ice cream and alcohol.

Pregnancy, breastfeeding and fertility

Safety of INTEFLORA 250 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 250.

Driving and using machines

INTEFLORA 250 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 250 does not adversely affect your ability to do so safely (see section 4).

INTEFLORA 250 contains lactose monohydrate

If you have been told by your doctor that you (your infant or child) have an intolerance to some sugars, contact your doctor before taking INTEFLORA 250.

3. HOW TO TAKE INTEFLORA 250

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

Always take INTEFLORA 250 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.

The usual dose of INTEFLORA 250 is:

Diarrhoea associated with antibiotic therapy

Adults: Take two capsules twice a day.

Infants and children: Give one capsule twice a day.

In infants and small children under 6 years of age, it is recommended not to swallow the capsule (due to the risk of choking), but to open it and add its contents to a food or sweetened drink.

Non-specific acute diarrhoea

Adults: Take one capsule twice a day.

Infants and children: Give one capsule twice a day.

In infants and small children under 6 years of age, it is recommended not to swallow the capsule (due to the risk of choking), but to open it and add its content to a food or sweetened drink.

INTEFLORA 250 may be taken in conjunction with antibiotics and other anti-diarrhoeal medication.

INTEFLORA 250 is for oral administration. The capsule must be swallowed with a glass of water.

In case the capsule is opened, the powder of the capsule must be stirred into water immediately prior to intake.

See section ‘INTEFLORA 250 with food and drink’.

If you take more INTEFLORA 250 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 250

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

4. Possible side effects

INTEFLORA 250 can have side effects.

Not all side effects reported for INTEFLORA 250 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking INTEFLORA 250, please consult your healthcare provider for advice.

If the following happens, stop taking INTEFLORA 250 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 250. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- 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).

Side effects with an unknown frequency:

- 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:** via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of INTEFLORA 250.

5. How to store INTEFLORA 250

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Do not store above 25 °C.

Store in the original container. The container should be tightly closed.

Protect from moisture and light.

Do not store in bathrooms.

Do not use INTEFLORA 250 after the expiry date stated on the label.

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 250 contains

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

The other ingredients are magnesium stearate; empty capsule shells: gelatin, titanium dioxide.

Contains sugar: Lactose monohydrate 32,5 mg per capsule

What INTEFLORA 250 looks like and contents of the pack

INTEFLORA 250 is a size 0, opaque white capsule.

Transparent and colourless glass bottle with a white plastic cap containing 10, 20 or 28 capsules or aluminium foil and aluminium/PVC blister packs of 4 or 20 capsules.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodmead

2191

Hotline: 0800 122 912

This leaflet was last revised in

13 November 2023

Registration number

T194 (Act1010/1965)

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

INTEFLORA is a registered trademark of Biocodex SAS. © 2023 Aspen Group of companies or its licensor. All rights reserved.

ZA_INTECAP_2311_00