

Infloran®

Hard capsules

Bifidobacterium bifidum + *Lactobacillus acidophilus*

Read all of this leaflet carefully before taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as directed by your doctor or healthcare professional.

- Keep this leaflet. You may need to read it again.
- Ask your healthcare professional if you need more information or advice.
- If you experience any side effects, talk to your doctor or healthcare professional. This includes any possible side effects not listed in this leaflet. **See section 4.**
- You must talk to your doctor if you do not feel better or if you feel worse after a few days.

What is in this leaflet

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

1. What Infloran is and what it is used for

Infloran contains *Bifidobacterium bifidum* and *Lactobacillus acidophilus*, microorganisms normally found in a healthy gut. These microorganisms play an important role in our gut health.

Infloran is used for

- Helping restore beneficial intestinal bowel flora in healthy children and healthy infants.
- Maintaining and supporting a healthy gastrointestinal immune function in adults, children and healthy infants.
- Helping to reduce and relieve diarrhoea in adults, children and healthy infants.
- Infloran helps promote and enhance a healthy digestive system function in formula fed healthy infants and healthy children under 2 years of age.

2. What you need to know before you take Infloran

Do not take Infloran

- if you are allergic to the active substances or any of the ingredients of this medicine (listed in section 6).

Seek medical advice if diarrhoea persists for more than: 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years.

Do not use for prolonged periods. Consult your doctor or healthcare professional if you do not notice any improvement after a few days. Consult your doctor or healthcare professional if the disorder returns or if you have noted any recent changes in the symptoms.

The colour of the product may change from one package to the next: this is due to the other ingredients in the medicine (listed in section 6) and does not mean that the product is altered.

Infants, children and adolescents

This medicine may be used for infants, children and adolescents.

Other medicines and Infloran

Tell your doctor or healthcare professional if you are taking, have recently taken or may take any other medicines.

Infloran with food, drink and alcohol

There are no known interactions. For how to take the medicine see section 3.

Pregnancy and breast-feeding

This medicine may be used during pregnancy and breast-feeding. If you have any doubt, ask your doctor or healthcare professional for advice before taking this medicine.

Driving and using machinery

Infloran does not influence the capacity to drive vehicles or use machinery.

Infloran contains sucrose and lactose.

If you have been told by your doctor or healthcare professional you have an intolerance to some sugars, contact them before taking this medicinal product.

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3. How to take Infloran

Always take this medicine exactly as your doctor or healthcare professional has directed. Check with your doctor or healthcare professional if unsure.

The recommended dose for adults is 1 capsule 3 times a day, before meals.

Swallow the capsule with a small amount of cold or lukewarm liquid.

Use in children

Follow the same doses recommended for adults.

For infants: 1 capsule 3 times a day or as directed by your doctor. Open the capsule and pour the content into a small amount of liquid (cold or lukewarm). It is recommended to take the preparation soon after.

It may be added to breast milk or formula.

How long to take

Use only for short periods or as directed by your doctor or healthcare professional.

Do not exceed the recommended doses without the advice of your doctor or healthcare professional.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody experiences them.

Infloran presents no known side effects when used at the recommended dose.

Compliance with the instructions contained in the package leaflet reduces the risk of side effects.

Reporting of side effects

If you experience any side effects, talk to your doctor or healthcare professional. This includes any possible side effects not listed in this leaflet. You can also report side effects directly on the website <https://www.infloran.com.au/reporting-adverse-events> or Tel: 1300 819 765

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

5. How to store Infloran

Store in a refrigerator (2°C – 8°C). Store in the original package to protect from light.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to discard of medicines you no longer use. These measures help protect the environment.

6. Contents of the pack and other information

What Infloran contains

In one capsule:

The active substances are:

Not less than 1 billion viable lyophilized *Bifidobacterium bifidum*,

Not less than 1 billion viable lyophilized *Lactobacillus acidophilus*.

The other ingredients are sucrose, sodium citrate, magnesium stearate, dipotassium phosphate, lactose monohydrate. The capsule shell contains: gelatin, titanium dioxide (E171), erythrosine (E127), indigotine (E132), quinolin yellow (E104).

What Infloran looks like and contents of the pack

Infloran is packaged in a box containing 20 hard capsules in blister packs. Appearance of capsule: Yellow / red hard capsules.

Manufacturer and Australian Sponsor

Manufacturer:

Laboratorio Farmaceutico SIT S.r.l.

Via Cavour 70 - 27035 Mede (PV) Italy

Australian sponsor:

Evidence Based Probiotics

Suite 4, 74 Prospect Road

Prospect SA 5082

www.infloran.com.au

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Laboratorio
Farmaceutico