

ORSBiotic™

Oral Rehydration Solution Combined with Probiotics

Consumer Medicine Information

1. What is in the leaflet?

This leaflet answers some common questions about ORSBiotic™ powder.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines and supplements have risks and benefits. Your doctor has weighed the risks of you taking ORSBiotic™ powder against the benefits they expect it will have for you.

If you have any concerns about taking this supplement, ask your doctor or pharmacist.

Keep this leaflet with the supplement.

You may need to read it again.

2. What ORSBiotic™ is used for

ORSBiotic™ is an Oral Rehydration Solution to replace fluids lost due to vomiting, diarrhoea, fever and strenuous physical activity.

ORSBiotic™ contains probiotic species, which assist to maintain healthy gastrointestinal homeostasis and permeability. The selected probiotic species from the genera *Saccharomyces*, *Lactobacillus* and *Bifidobacterium* have clinical evidence for providing therapeutic support for various triggers of diarrhoea including infectious agents, antibiotic-associated and *Clostridium difficile*-associated diarrhoea and may help reduce the frequency and duration of diarrhoea. Zinc supplementation has been found to reduce the duration and severity of diarrhoea in children.

Your healthcare professional or pharmacist may have prescribed ORSBiotic™ for another reason.

Ask your healthcare professional or pharmacist if you have any questions concerning why ORSBiotic™ as been prescribed for you.

ORSBiotic™ is not addictive.

3. Before you take ORSBiotic™

3a) When you **MUST NOT** take it

Do not take ORSBiotic™ if:

1. You have had an allergic reaction to ORSBiotic™ or any ingredient listed in section 8b.

2. The packaging is torn, missing or shows signs of tampering

3. The expiry date (EXP) printed on the pack has passed. If it has expired or is damaged, return it to your pharmacist for disposal.

If you take this supplement after the expiry date has passed, it may not work as well.

If you are not sure if you should start taking ORSBiotic™ contact your healthcare professional or pharmacist.

3b) Before you start to take it

You must tell your doctor if:

1. You have any allergies to any other medicines, foods, preservatives, dyes or additives.

ORSBiotic™ contains sodium chloride, potassium citrate, citric acid anhydrous, glucose anhydrous, zinc gluconate and four probiotic bacteria.

If you experience any allergic reaction or other side effects after consuming ORSBiotic™ you should discontinue use and consult with your healthcare professional or pharmacist.

2. You are pregnant or planning to become pregnant

3. You are breastfeeding or planning to breastfeed

4. You have or have had any other health problems or issues including:

- Gastrointestinal conditions
- Compromised immune system (HIV/ AIDS or during chemotherapy treatment)
- Short bowel syndrome

If you have not told your healthcare professional or pharmacist about any of the above, tell them before you start taking ORSBiotic™

3c) Taking other medicines

Tell your healthcare professional or pharmacist if you are taking any other medicines, including any that you get without a prescription from a naturopath, supermarket or health food store.

Some medicines may be affected by ORSBiotic™ or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your healthcare professional or pharmacist has more information on medicines to be careful with or avoid while taking ORSBiotic™

4. How to take ORSBiotic™

4a) How much to take

Follow all directions given to you by your healthcare professional or pharmacist carefully.

Take ORSBiotic™ exactly as your healthcare professional or pharmacist has prescribed.

They may differ from the information contained in this leaflet.

4b) How much ORSBiotic™ should be taken?

Add 5 g of powder (1 scoop) to 200 mL of cold water immediately before use and stir well or as directed by your healthcare professional.

Your healthcare professional or pharmacist will tell you how much ORSBiotic™ powder to take each day. This depends on the condition being treated and whether any other medicines are being used.

4c) How to take ORSBiotic™

Powder should be dissolved into cold water and sipped frequently. Un-used preparation is to be *kept refrigerated*. Discard all unused reconstituted preparation if more than 12 hours.

4d) When to take ORSBiotic™

Recommended dose for under 3 years is 100 mL every 90 minutes; 3-6 years 100 mL every 60 minutes; 6-12 years 100 mL every 30 minutes and over 12 years 200 mL every 30 minutes.

4e) How long to take ORSBiotic™

Take ORSBiotic™ as long as your healthcare professional prescribes.

4f) If you forget to take ORSBiotic™

Do not try to make up for missed doses by taking an extra dose.

This may increase the chance of getting an unwanted side effect.

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

If you are unsure of what to do, check with your healthcare professional or pharmacist.

4g) If you have taken too much ORSBiotic™ (overdose)

Visit your healthcare professional or pharmacist as soon as possible. Tell them how much ORSBiotic™ you took and he/she can determine what action is best for your health. Please visit your healthcare professional or pharmacist if there are signs of discomfort or poisoning.

5. While you are taking ORSBiotic™

5a) Things you **MUST** do:

If you become pregnant while taking, ORSBiotic™ tell your healthcare professional or pharmacist immediately.

If you are about to start taking a new medicine, tell your healthcare professional or pharmacist that you are taking ORSBiotic™.

Always follow your healthcare professional or pharmacist's instructions carefully.

5b) Things you **MUST NOT** do

Do not heat ORSBiotic™ or add into hot liquids or foods.

Do not expose ORSBiotic™ to extreme heat conditions for extended periods of time.

5c) Things to be careful of

As ORSBiotic™ contains probiotic species, taking antibiotics along with probiotics can reduce their effectiveness. To avoid this interaction take ORSBiotic™ at least 2 hours before or after antibiotics.

You should discuss this with your healthcare professional.

6. Side Effects

All medicines and supplements can have side effects. Sometimes they are serious, most of the time they are not.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your healthcare professional or pharmacist to answer any questions you may have.

Tell your healthcare professional or pharmacist if you notice any of the following and they worry you:

- Cramps or pain in the stomach area
- Diarrhoea
- Mucus in the stool
- Bloating stomach area
- Gas

These side effects are usually mild and dose related. Most of them disappear completely in a few days after the dose of ORSBiotic™ is lowered or stopped.

Serious allergic reactions to these ingredients are rare; however tell your healthcare professional or pharmacist immediately if you experience any of the following:

- Skin rash
- Swelling of the face and/or mouth
- Difficulty breathing
- Itching of the skin

If symptoms persist consult your healthcare practitioner. 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 children over 6 years and adults, seek medical advice.

Contains glucose (sugar). This powder contains zinc which may be dangerous if taken in large amounts or for a long period.

7. After taking ORSBiotic™

7a) Storage

Keep ORSBiotic™ in its bottle until it is time to take it. If you take the powder out of the bottle it may not keep well.

Always store ORSBiotic™ only in its original container. Store below 25°C. Recommended to keep refrigerated. Do not freeze.

Do not store ORSBiotic™, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy the medicine.

Keep out of reach from children.

Protect ORSBiotic™ from light.

8. Product description

8a) What ORSBiotic™ looks like

ORSBiotic™ is an orange powder. It is in a white cylinder bottle and each bottle contains 100g of powder (20 doses).

8b) Ingredients

Active Ingredients per 5 g (1 scoop) dose

<i>Saccharomyces cerevisiae</i> ssp. <i>boulardii</i> (Med 41).....	2 billion
<i>Lactobacillus gasseri</i> (Med 23).....	2 billion
<i>Lactobacillus plantarum</i> (Med 25).....	2 billion
<i>Bifidobacterium breve</i> (Med12).....	2 billion
Sodium Chloride	533.2 mg
Equiv. Sodium.....	209.7 mg
Equiv. Chloride.....	323.5 mg
Potassium Citrate.....	449.1 mg
Equiv. Potassium.....	162.6 mg
Equiv. Citrate.....	261.8 mg
Glucose Anhydrous.....	2.5 g
Citric Acid Anhydrous.....	890.5 mg
Zinc Gluconate.....	44.8 mg
Equiv. Zinc.....	6.4 mg

Excipient Ingredients

Silica
Stevia
Thaumatococcus
Orange flavour
Carrot powder

ORSBiotic™ does not contain any artificial colours, flavours or sweeteners

ORSBiotic™ is suitable for vegetarians

ORSBiotic™ is gluten and dairy free

9. Translation

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10. Manufacturer

ORSBiotic™ is supplied in Australia by:
A division of Medlab Clinical Limited™

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Alexandria NSW 2015
Toll free: 1300 369 570

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AUST L 239102
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Medlab Clinical Limited™