

Product Information Leaflet
DualBalance™



SCHEDULING STATUS: None
PROPRIETARY NAME (AND DOSAGE FORM):
DualBalance™ (powder for reconstitution)

COMPOSITION:

Each sachet contains: probiotics, prebiotic and electrolytes.

Composition of Probiotics and Prebiotic per sachet

A probiotic mixture consists of *Lactobacillus acidophilus*, *Lactobacillus rhamnosus*, *Bifidobacterium bifidum* and *Bifidobacterium lactis* (in a lyophilised form). The mixture in total yields not less than 21 billion (10⁹) viable cells. The mixture also contains a prebiotic, namely: 1g of fructo-oligosaccharide.

Composition of Electrolytes

Glucose	3.5 g/sachet
Sodium chloride	0.65 g/sachet
Potassium chloride	0.375 g/sachet
Sodium citrate	0.8 g/sachet

PHARMACOLOGICAL ACTION:

INDICATIONS:

DualBalance™ is a formulation comprising probiotics, a prebiotic and electrolytes.

Probiotics: "When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract" (Schedule 0).

Prebiotic: FOS (Fructo-oligosaccharide) beneficially affects the intestinal flora by selectively stimulating the growth of the beneficial gut micro-organisms, thus positively affecting intestinal health (Schedule 0).

Oral Rehydration Formula (ORF) is a fluid replacement formula, used to prevent or treat dehydration, most commonly caused by diarrhoea. It involves drinking water with modest amounts of sugar and salt.

Electrolyte maintenance is important to assist in the prevention of dehydration:

- Introducing electrolytes back into the body, helps keep dehydration from occurring.
- Electrolytes assist with the absorption of fluids.
- Formulations that contain glucose, sodium chloride, potassium chloride and sodium citrate can assist with replenishing lost electrolytes.

CONTRA-INDICATIONS AND WARNINGS:

- Do not use **DualBalance™** if allergic to any of the ingredients contained in this product.
- The diagnosis of dehydration requires an assessment by a healthcare practitioner.
- Those who have a suppressed immune system should take probiotics under medical supervision.
- The product has not been evaluated in pregnant women and lactating mothers. Women who are pregnant or breastfeeding should consult a healthcare professional before using this product.
- If vomiting and/or diarrhoea continue for more than 2 days, a healthcare professional should be consulted.

INTERACTIONS:

There are no reported medicinal interactions.

DOSAGE AND DIRECTIONS FOR USE:

Tear the sachet open and empty the contents of both pouches into a glass or water bottle, add 250 ml of clean water and stir until the powder is dissolved. **Do not use warm or boiling water, as this will affect the probiotics in a negative way.** Boiled water must be

cooled down before use. Any unused solution must be discarded.

For Adults:

- Give 250 ml of reconstituted **DualBalance™** after each bowel movement.
- If large amounts are difficult to tolerate, the preparation may also be given in smaller amounts more frequently.
- To speed up the process of rehydration, clean water should also be taken regularly.
- If the person is hungry, small amounts of food may be given on a regular basis.

For Children:

DualBalance™ is suitable for use by children 1 year old and older.

- Give 50-250 ml of reconstituted **DualBalance™** after each bowel movement.
- If large amounts are difficult to tolerate, the preparation may also be given in smaller amounts more frequently.
- To speed up the process of rehydration, clean water should also be taken regularly.
- If the child is hungry, small amounts of food may be given on a regular basis.
- Vomiting seldom prevents successful rehydration, since much of the fluid is still absorbed. If the patient vomits, the World Health Organisation (WHO) recommends taking a break of 5 to 10 minutes and then restarting the administration of the solution slower. For example, a child under the age of 2 can be given a teaspoonful of fluid every 2 to 3 minutes.
- Oedematous (puffy) eyelids are a sign of over-hydration. If this occurs, stop giving **DualBalance™** and continue to give clean water. Consult a healthcare practitioner immediately.
- The solution should be given using the most comfortable application method: a clean spoon, dropper or syringe (without a needle) can be used effectively to administer small amounts of the **DualBalance™** solution.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Large doses of probiotics may cause loose stools in some individuals.

Please refer to contra-indications and warnings.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Loose stools whereupon the administration of **DualBalance™** should be discontinued temporarily.

IDENTIFICATION:

DualBalance™ is available in two flavours:

A cream to off-white powder with an orange flavour.

A cream to off-white powder with a pineapple-grapefruit flavour.

PRESENTATION:

Carton with 5 sachets.

STORAGE INSTRUCTIONS:

Store in a cool, dry place below 25° C.

Keep out of reach of children.

DATE OF PUBLICATION OF THIS PRODUCT LEAFLET: April 2015

NAME AND BUSINESS ADDRESS OF APPLICANT:

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Packed by: Creative Care Solutions (Pty) Ltd

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Produk Inligtingspamflet DualBalance™



SKEDULERINGSSTATUS: Geen
EIENDOMSNAAM (EN DOSEERVORM):
DualBalance™ (poeier vir hersamestelling)

SAMESTELLING:

Elke sakkie bevat: probiotika, 'n prebiotikum en elektroliete.

Samestelling van die Probiotika en die Prebiotikum per sakkie

'n Probiotiese mengsel bestaande uit *Lactobacillus acidophilus*, *Lactobacillus rhamnosus*, *Bifidobacterium bifidum* en *Bifidobacterium lactis* (in 'n geliofiliseerde vorm). Die mengsel in totaal bevat nie minder as 21 biljoen (10⁹) lewensvatbare selle nie. Die mengsel bevat ook 'n prebiotikum, naamlik: 1g frukto-oligosakkaried.

Samestelling van Elektroliete

Glukose	3.5 g/sakkie
Natriumchloried	0.65 g/sakkie
Kaliumchloried	0.375 g/sakkie
Natriumsitraat	0.8 g/sakkie

FARMAKOLOGIESE WERKING:

INDIKASIES:

DualBalance™ is 'n formulering wat probiotika, 'n prebiotikum en elektroliete bevat.

Probiotika: "Wanneer dit gereeld ingeneem word, behoort probiotika die mikrobiale balans in die menslike spysverteringskanaal te verbeter en te normaliseer, en dus die funksionering van die spysverteringskanaal te verbeter." (Skedule 0).

Prebiotikum: FOS (Frukto-oligosakkaried) het 'n voordelige effek op die intestinale flora, deurdat dit die groei van die voordelige mikroörganismes van die spysverteringskanaal selektief stimuleer, waardeur die gesondheid van die spysverteringskanaal positief beïnvloed word (Skedule 0).

Orale Rehidrasieformulasie (ORF) is 'n vloeistofvervangingsformulasie wat gebruik word om dehidrasie, wat oor die algemeen deur diarree veroorsaak word, te voorkom of te behandel. Dit vereis dat water met matige hoeveelhede suiker en sout gedrink word.

Die handhawing van **Elektroliete** is belangrik om dehidrasie te help voorkom:

- Invoering van elektroliete terug in die liggaam help om die voorkoms van dehidrasie te verhoed.
- Elektroliete help met die absorpsie van vloeistowwe.
- Formulerings wat glukose, natriumchloried, kaliumchloried en natriumsitraat bevat, kan help om verlore elektroliete te vervang.

KONTRA-INDIKASIES EN WAARSKUWINGS:

- Moet nie **DualBalance™** neem indien jy vir enige van die bestanddele wat die produk bevat, allergies is nie.
- Die diagnose van dehidrasie verg evaluering deur 'n gesondheidspraktisyn.
- Persone wat 'n onderdrukte immuunsisteem het, behoort probiotika onder mediese toesig te neem.
- Die produk is nie in swanger vrouens en lakterende moeders geëvalueer nie. Vrouens wat swanger is of borsvoed, behoort 'n geneesheer te raadpleeg voordat hulle hierdie produk gebruik.
- Indien braking en diarree vir langer as 2 dae aanhoudend voorkom, moet 'n geneesheer geraadpleeg word.

INTERAKSIES:

Geen medisinale interaksies is aangemeld nie.

DOSIS EN GEBRUIKSAANWYSINGS:

Skeur die sakkie oop en gooi die inhoud van beide sakkies in 'n glas of waterbottel, voeg 250 ml skoon water by en roer totdat die poeier opgelos het. **Moet nie**

warm of kokende water gebruik nie, want dit sal die probiotika op 'n negatiewe wyse affekteer.

Gekookte water moet afgekoel word voor gebruik. Enige ongebruikte oplossing moet weggegooi word.

Vir Volwassenes:

- Gee 250 ml van hersaamgestelde **DualBalance™** na elke ontlasting.
- Indien groot hoeveelhede moeilik verdra word, mag die preparaat ook in kleiner hoeveelhede, meer gereeld gegee word.
- Om die proses van rehidrasie te bespoedig, moet skoon water ook gereeld geneem word.
- Indien die persoon honger is, kan klein hoeveelhede kos op 'n gereelde basis gegee word.

Vir Kinders:

DualBalance™ is geskik vir gebruik deur kinders 1 jaar oud en ouer.

- Gee 50-250 ml hersaamgestelde **DualBalance™** na elke ontlasting.
- Indien groot hoeveelhede moeilik verdra word, mag die preparaat ook in kleiner hoeveelhede, meer gereeld gegee word.
- Om die proses van rehidrasie te bespoedig, moet skoon water ook gereeld geneem word.
- Indien die kind honger is, kan klein hoeveelhede kos op 'n gereelde basis gegee word.
- Braking verhoed selde suksesvolle rehidrasie, omdat baie van die vloeistof tog nog geabsorbeer word. Indien die pasiënt braak, beveel die Wêreld Gesondheidsorganisasie (WGO) aan dat daar vir 5 tot 10 minute gewag moet word en dat die toediening van oplossing dan stadiger hervat moet word. Byvoorbeeld, 'n kind jonger as 2 jaar, kan 'n teelepel vloeistof elke 2 tot 3 minute gegee word.
- Edeemagtige (pofferige) ooglede is 'n teken van oorhidrasie. Indien dit sou voorkom, staak toediening van **DualBalance™** en gaan voort om skoon water te gee. Raadpleeg jou geneesheer dadelik.
- Die oplossing behoort gegee te word deur van die mees gemaklikste metode van toediening gebruik te maak: 'n skoon lepel, drupper of spuit (sonder 'n naald) kan effektief gebruik word om klein hoeveelhede van die **DualBalance™** oplossing toe te dien.

NEWE-EFFEKTE EN SPESIALE

VOORSORGMATREËLS:

Groot dosisse probiotika kan los stoelgang by sommige individue veroorsaak.

Verwys asseblief na kontra-indikasies en waarskuwings.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Los stoelgange, waarna die toediening van **DualBalance™** tydelik gestaak moet word.

IDENTIFIKASIE:

DualBalance™ is beskikbaar in twee geure:

'n Room tot naaswit poeier met 'n lemoengeur.

'n Room tot naaswit poeier met 'n pynappel-pomeloëur.

AANBIEDING:

Kartonverpakking met 5 sakkies.

BERGINGSINSTRUKSIES:

Berg in 'n koel, droë plek onder 25° C.

Hou buite bereik van kinders.

DATUM VAN PUBLIKASIE VAN HIERDIE PRODUK INLIGTINGSPAMFLET: April 2015

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