b.wellness

PACKAGE LEAFLET: INFORMATION FOR THE USER

SCHEDULING STATUS

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PROPRIETARY NAME (and dosage form)

B-Wellness Gut Restore & Debloat Tablets 60's

ACTIVE INGREDIENTS:

EACH SERVING CONTAINS:	mg PER 2 TABs	%NRV*
Probiotic 9-strain blend Providing a total of 4.5x10 ⁹ CFU of: Lactobacillus Acidophilus Lactobacillus Casei Lactobacillus Rhamnosus Lactobacillus Plantarum Bifidobacterium Bifidum Bifidobacterium Longum Bifidobacterium Lactis Streptococcus Thermophilus Lactococcus Lactis	500	**
Inulin	400	**
Foeniculum Vulgare (Fennel) [Fruit, as a 10:1 extract]	40	**
DigeZyme™ (Digestive Enzyme Blend) Providing: Alpha Amylase 6000DU Neutral Protease 1500PC Cellulase 275CU Lactase 1000ALU Lipase 65FIP	250	**
Brassica Oleracea (Broccoli) [Leaf & florets, as a 10:1 extract]	25	***
L-Glutamine	200	**
Zingiber Officinale (Ginger) [Root, as a 4:1 extract]	20	***
Plantago Ovata (Psyllium Husk/lsphagula) [Seeds, as powder]	20	***
Curcuma Longa (Turmeric) [Root, as powder standardised to 95% Curcuminoids] Providing: Curcuminoids	20 19	**

* NRV (Nutrient Reference Values for persons 4 years and older) ** No NRV established *** DHE = Dried Herb Equivalent

Contains No Sugar, Non-nutritive Sweeteners, colourant or flavourant

Excipients: Micro Crystalline Cellulose, Magnesium Stearate, Silicon Dioxide

Category D **Complementary Medicine** Discipline: Western Herbal Medicine

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

Read all of this leaflet carefully because it contains important information for you. Keep this leaflet. You may need to read it again.

B-Wellness Gut Restore & Debloat Tablets is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use B-Wellness Gut Restore & Debloat Tablets carefully to get the best results from it.

Do not share B-Wellness Gut Restore & Debloat Tablets with any other person.

Ask your healthcare provider or Pharmacist if you need more information or advice.

What is in this leaflet?

- 1. What B-Wellness Gut Restore & Debloat Tablets is, and what it is used for
- 2. What you need to know before you take B-Wellness Gut Restore & Debloat Tablets
- 3. How to take B-Wellness Gut Restore & Debloat Tablets
- 4. Possible side effects
- 5. How to store B-Wellness Gut Restore & Debloat Tablets
- 6. Contents of the pack and other information

1. What B-Wellness Gut Restore & Debloat Tablets is, and what it is used for

The active ingredients of B-Wellness Gut Restore & Debloat Tablets include Pre- and Pro-Biotics to improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract. Psyllium Husk helps to maintain regular, healthy bowel movements while fennel seeds may reduce bloating. Ginger may stimulate the flow of bile while reducing colic, indigestion and pain from irritable bowel syndrome and other inflammatory bowel conditions. Curcumin may prevent or alleviate inflammatory bowel conditions such as colitis, ulcerative colitis, irritable bowel syndrome or Crohn's disease as well as pancreatitis.

Possible indications for B-Wellness Gut Restore & Debloat Tablets include:

- Support healthy digestion and absorption
- Reduce intestinal inflammation
- · Reduce colic, bloating and intestinal discomfort
- Source of amino acid
- · Replenish intestinal micro-biome daily or after anti-biotic use

2. What you need to know before you take B-Wellness Gut Restore & Debloat Tablets

Do not take B-Wellness Gut Restore & Debloat Tablets:

- If you are hypersensitive (allergic) to any of the active ingredients or any of the other ingredients of B-Wellness Gut Restore & Debloat Tablets (listed in section 6)
- If you have been diagnosed with gallstones or a bile duct obstruction (due to the Curcumin content)
- If you are pregnant or breast feeding (Curcumin)
- If you are severely immunocompromised or immunosuppressed (Pro-Biotics)

Warnings and precautions

Keep out of reach of children.

Unless otherwise prescribed, do not exceed the stated daily dose.

Sufficient protein is provided in normal well-balanced daily meals.

If you are using ANY prescribed medication FIRST consult your Doctor or Pharmacist before using B-Wellness Gut Restore & Debloat Tablets.

If symptoms develop, worsen or persist, consult a relevant health care provider. Not suitable for children unless under the care of a relevant health care provider. Consult a relevant health care provider prior to use (due to the Curcumin content) if you:

- are pregnant;
- are taking antiplatelet medication or blood thinners;
- · have gallstones or a bile duct obstruction; or
- have stomach ulcers or excess stomach acid.

Consult a relevant health care provider prior to use (due to the L-Glutamine content) if you are following a low protein diet.

Other medicines and B-Wellness Gut Restore & Debloat Tablets

Always tell your healthcare provider if you are taking any other medicine. Curcumin may potentially interact with CYP2D6 and CYP3A substrates. Consult your health care provider prior to use. See Warnings and Precautions.

B-Wellness Gut Restore & Debloat Tablets with food

Taking B-Wellness Gut Restore & Debloat Tablets with food may assist in increasing the number of live pro-biotics and active enzymes to reach the small intestine.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, do not use this medicine as Curcumin may have emmenagogue (increase vomiting) and abortifacient (increase the risk of spontaneous abortion) effects.

Safety in pregnancy has not been established.

3. How to take B-Wellness Gut Restore & Debloat Tablets

Do not share medicines prescribed for you, with any other person. Take B-Wellness Gut Restore & Debloat Tablets exactly as described in this leaflet or as prescribed by your Doctor or Pharmacist.

Dosage and Directions for use

Adults: Take 2 tablets daily preferably in the morning before breakfast, or as prescribed by your Doctor or Pharmacist. Not suitable for use in Children. Do not exceed the stated daily dosage.

If you take more B-Wellness Gut Restore & Debloat Tablets than you should,

you may experience headache, heart arrhythmias, increased bleeding, breathing difficulties or gastrointestinal symptoms such as heartburn, bloating, diarrhoea, nausea or abdominal cramping. In the event of overdosage, stop using B-Wellness Gut Restore & Debloat Tablets and consult your doctor or Pharmacist. If neither is available, contact the nearest hospital or poison centre. If you forget to take B-Wellness Gut Restore & Debloat Tablets, do not take a double dose to make up for forgotten doses.

4. Possible side effects

B-Wellness Gut Restore & Debloat Tablets can have side effects.

Not all side effects reported for B-Wellness Gut Restore & Debloat Tablets are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking B-Wellness Gut Restore & Debloat Tablets, please consult your healthcare provider for advice.

If any of the following happens, stop taking B-Wellness Gut Restore & Debloat Tablets and tell your doctor:

• Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,

- Rash or itching,
- Diarrhoea, nausea or vomiting,
- Difficulty breathing, tightness of chest or throat, chest pain or arrhythmias,
- Increased bleeding.

5. How to store B-Wellness Gut Restore & Debloat Tablets

Store all medicines out of reach of children.

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

6. Contents of the pack and other information

What B-Wellness Gut Restore & Debloat Tablets contains

- The active ingredients of B-Wellness Gut Restore & Debloat Tablets are (per 2 tablets): 9-strain Probiotic Blend [see table of ingredients, total 4.95 billion CFU] (500 mg), Inulin (400 mg), DigeZyme® [see table of ingredients] (250 mg), L-Glutamine (200 mg), Fennel Seed [Fruit] (40 mg), Broccoli [Leaf & florets] (25 mg), Ginger [Root] (20 mg), Psyllium Husk [Seeds] (20 mg) and Curcumin [Root] (19 mg)
- Excipients: Micro Crystalline Cellulose, Magnesium Stearate, Silicon Dioxide

What B-Wellness Gut Restore & Debloat Tablets looks like and contents of the pack

- Pale yellow-speckled, scored oval tablet (20 mm length)
- 60 tablets in a 140 ml glass frosted amber jar with 38 mm aluminum PRET screw cap

Applicant:

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This leaflet was created in:

November 2022

PI available from:

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