Professional Information for BOUNCEBACK®

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
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1. NAME OF THE MEDICINE
BOUNCEBACK® CAPSULES

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each capsule contains:

Curcuma longa L. (Turmeric)	100 mg
[rhizome, 50:1 extract, standardised to 95 % curcuminoids]	
Curcuma longa L. (Turmeric)	100 mg
[rhizome, 25:1 extract, standardised to 95 % curcuminoids]	
Avocado soy unsaponifiables	150 mg
providing 30 % phytosterols	(45 mg)
Proteolytic enzyme blend	129 mg
Bromelain	(104 mg)
[pineapple stem juice]	
Protease	(25 mg)
(from *Aspergillus melleus & Aspergillus oryzae*)	
Ascorbyl palmitate (Vitamin C)	10 mg
Resveratrol (*Polygonum cuspidatum*)	0,6 mg
[root, 30:1 extract standardised to resveratrol 20 %, providing 3 mg of dried herb equivalent]	

Sugar free.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Hard capsules.
Orange powder in a clear capsule.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
BOUNCEBACK® is a combination complementary medicine intended to assist the body with recovery from physical activity.

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4.2 Posology and method of administration

Adults: Take 2 capsules once daily with a glass of water on an empty stomach, at least 45 minutes before or two hours after a meal. Allow 4 to 6 weeks for optimal benefits.
Do not exceed the recommended dosage.

4.3 Contraindications

Hypersensitivity to any of the ingredients listed in section 2 or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use Surgery:

BOUNCEBACK® might interfere with blood glucose control and increase the risk of bleeding during and after surgical procedures. Patients should be advised to discontinue BOUNCEBACK® at least 2 weeks prior to any surgical procedures (see section 4.5).

Pineapple allergy:

Patients allergic to pineapple might have an allergic reaction to BOUNCEBACK®.

Renal, pancreatic and gastrointestinal conditions:

Patients should consult a health care provider prior to use if they have gallstones, a bile duct obstruction, stomach ulcers, excess stomach acid or gastrointestinal lesions or want to use BOUNCEBACK® for a prolonged period.

Other conditions:

Patients should consult with a relevant health care provider prior to use, especially if they:

- are pregnant or breastfeeding (see section 4.6);
- are taking prescription medicine, as BOUNCEBACK® may alter the effectiveness of these medications; and
- have hormone sensitive conditions.

If hypersensitivity/allergy, nausea, vomiting or diarrhoea is experienced after taking BOUNCEBACK®, patients should stop taking BOUNCEBACK®.

4.5 Interaction with other medicines and other forms of interaction

Anticoagulant or antiplatelet medicines:

BOUNCEBACK® may potentiate the effects of anticoagulant and antiplatelet medicines or herbal supplements with blood thinning effects (see section 4.4).

Antidiabetic medicines:
Concomitant use of BOUNCEBACK® with antidiabetic medicines or herbal supplements with blood sugar lowering effects may interfere with blood glucose control and caution is advised during concomitant use (see section 4.4).

Antibiotics and anti-inflammatory medicines:
Patients taking anti-inflammatory medicines or antibiotics should consult a health care provider prior to use.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established (see section 4.4).

4.7 Effects on ability to drive and use machines

BOUNCEBACK® is unlikely to affect the ability to drive and use machines.

4.8 Undesirable effects

Immune system disorders:

Less frequent:	hypersensitivity/allergic reactions

Gastrointestinal disorders:

Frequent:	diarrhoea, gastric upset, abdominal cramps, heartburn, nausea, vomiting, constipation, distension.
Less frequent:	stomach pain, regurgitation, dyspepsia

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of BOUNCEBACK® is important. It allows continued monitoring of the benefit/risk balance of BOUNCEBACK®. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications:
https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8). In the event of overdose, treatment should be symptomatic
and supportive.

5. PHARMACOLOGICAL PROPERTIES

Category and class: D 33.7 Combination Product.

Mechanism of action:

Avocado soy unsaponifiables has anti-inflammatory and antioxidant properties.

Bromelain is a digestive enzyme obtained from the fruit and stem of a pineapple, with anti-inflammatory properties.

Turmeric aids in digestion and is used as an anti-inflammatory to help relieve joint pain.

Protease is a digestive enzyme that helps with the digestion of proteins.

Resveratrol has anti-inflammatory and antioxidant properties.

Vitamin C is an antioxidant for the maintenance of good health.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium silicate (E552).
Capsule (containing hypromellose).
Magnesium stearate (E572).
Microcrystalline cellulose (E460(i)).
Silicon dioxide (E551).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C, in a dry place.
Keep the bottle tightly closed.
Do not use if inner seal is missing or broken.

6.5 Nature and contents of container

HDPE container with a polypropylene cap containing 60 capsules.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Mannatech South Africa (Pty) Ltd
Viscount Office Park, 11 Viscount Road
Bedfordview, Gauteng 2007
South Africa

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

June 2021.

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