Professional Information for IMMUNOSTART®

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

SCHEDULING STATUS
S0

1. NAME OF THE MEDICINE
IMMUNOSTART® TABLETS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each chewable tablet contains:

Bovine colostrum (Colostrum) [powder]	155 mg
Beta-glucan	16 mg
Pectin	15 mg

Excipients with known effect:
Contains sugar (1 218 mg dextrose per tablet).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Chewable tablets.
Off-white, round, chewable tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
IMMUNOSTART® is a complementary medicine intended to support immune function within the upper respiratory tract and assists with the maintenance of a healthy immune system.

4.2 Posology and method of administration
Adults: Take one tablet 3 times daily. Thoroughly chew each tablet before swallowing.

Do not exceed the recommended dosage.

Children: Not indicated for children younger than 18 years.

For prolonged use, a relevant health care provider should be consulted.

4.3 Contraindications

- Hypersensitivity to colostrum, beta-glucan, pectin or to any of the excipients listed in section 6.1.
- Known allergy to cow's milk.

4.4 Special warnings and precautions for use

IMMUNOSTART® is not a breast milk substitute. It contains lactose and cow's milk proteins. Patients with a known allergy to cow's milk should not use IMMUNOSTART®.

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

- are pregnant or breastfeeding (see section 4.6);
- have diabetes or a history of cancer;
- have liver or kidney disease or if they have been instructed to follow a low protein diet; or
- suffer from an immune system disorder (e.g. Crohn's disease, myasthenia gravis, multiple sclerosis, rheumatoid arthritis, systemic lupus erythematosus, HIV/AIDS, etc.) or if they are taking immunosuppressants.

4.5 Interaction with other medicines and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

MANNA CLEANSE® 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: nausea, vomiting, mild cramps, diarrhoea

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of IMMUNOSTART® is important. It allows continued monitoring of the benefit/risk balance of IMMUNOSTART®. 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 34.13 Other.

Mechanism of action:
Colostrum is the milky fluid produced by cows within the first few days after giving birth. Colostrum helps to support immune function within the upper respiratory tract and assists with the maintenance of a healthy immune system.

Beta-glucan and pectin provides soluble fibre for the maintenance of good health.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dextrose
Flavourants (strawberry)
Magnesium stearate (E572)
Malic acid (E296)
Maltodextrin
Silicon dioxide (E551)
Stearic acid (E570).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

12 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

White polyethylene (PE) bottle with a white polypropylene cap.
Pack size: 60 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

LeBasi Pharmaceuticals (Pty) Ltd
San Domenico Building, Ground Floor, Unit 6
10 Church Street
Durbanville, 7551
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

February 2022.

MANNATECH