Professional Information for PLUS™

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT
(WESTERN HERBAL MEDICINE / HEALTH SUPPLEMENT)
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS

S0

1. NAME OF THE MEDICINE

PLUS™ TABLETS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Dioscorea villosa L. (Wild Yam)	200 mg
[root, extract standardised to 12,5 % diosgenin (25 mg)]	
Glycine	200 mg
L-Glutamic acid	200 mg
L-Lysine (from L-Lysine HCl)	200 mg
L-Arginine (from L-Arginine HCl)	95 mg
Beta-sitosterol (from phytosterols)	25 mg
Boron glycine	10 mg
providing Boron	1 mg
Ambrotose® Complex	2,5 mg
providing *Larix laricina* (Du Roi) K. Koch or *Larix occidentalis* Nutt. (Larch Arabinogalactan)	(1,5 mg)
Manapol® *Aloe vera* (L.) Burm.f. (Aloe) [inner leaf juice powder]	(0,5 mg)
Astragalus gummifer Labill. (Tragacanth)	(0,5 mg)

Sugar free.

Excipients with known effects:
Contains sugar alcohol (7,74 mg xylitol per tablet).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.
Off-white to yellow, elongated film-coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

PLUS™ is a complementary medicine intended to assist the function of the endocrine system.

MANNATECH®

4.2 Posology and method of administration

Adults:
Take one tablet with 250 mL of water or juice, three times per day.
Do not exceed the recommended dosage.

Children:
Not suitable for children under the age of 18 years.

4.3 Contraindications

- Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 2 or 6.1.
- Abnormal constrictions of the gastrointestinal tract, potential or existing intestinal blockage, atonic bowel, appendicitis, inflammatory colon disease (e.g. Crohn's disease or ulcerative colitis), abdominal pain of unknown origin, undiagnosed rectal bleeding, severe dehydration with depleted water or electrolytes, haemorrhoids or diarrhoea.
- Pregnancy or lactation (see section 4.6).

4.4 Special warnings and precautions for use

Surgery:
PLUS™ may interfere with glucose and blood pressure control during and after surgical procedures. Patients should be advised to discontinue PLUS™ at least 2 weeks prior to any surgical procedures.

Gastrointestinal conditions:
Patients with faecal impaction or symptoms such as abdominal pain, nausea, vomiting or fever should consult a health care provider prior to use.

If abdominal pain, cramps, spasms and/or diarrhoea is experienced after taking PLUS™, patients should stop taking PLUS™ or reduce the dose.

Kidney and blood disorders:
Patients with a kidney disorder should consult a health care provider prior to use.

Cardiovascular disorders:
Patients with cardiovascular disease, hypotension, or a history of a myocardial infarction (MI) should consult a health care provider prior to use.

Low protein diet:
Patients following a low protein diet should consult a health care provider prior to use.

4.5 Interaction with other medicines and other forms of interaction

Anticoagulant or antiplatelet medicines:
PLUS™ may potentiate the effects of anticoagulant or antiplatelet medicines or herbal supplements with blood thinning effects. Concomitant use may increase the risk of bruising and bleeding.

Antihypertensive medicines:
The use of PLUS™ with antihypertensive medicine or herbal supplements with hypotensive effects may have additive blood pressure-lowering effects when used concomitantly. Caution is advised.

Patients taking cardiac medicines (e.g. cardiac glycosides or antidysrhythmic medicines), thiazide diuretics, corticosteroids, liquorice root, or other medicines or health products that may aggravate electrolyte imbalance, should consult a health care provider prior to use.

4.6 Fertility, pregnancy and lactation

PLUS™ should not be used during pregnancy and lactation (see section 4.3).

4.7 Effects on ability to drive and use machines

PLUS™ is unlikely to affect the ability to drive and use machines. Caution is advised when driving a vehicle or operating machinery until the effects of PLUS™ are known.

4.8 Undesirable effects

PLUS™ is generally well tolerated.

Immune system disorders:
Frequency unknown: hypersensitivity and/or allergic reactions.

Metabolism and nutrition disorders:
Frequency unknown: reduced appetite.

Psychiatric disorders:
Frequency unknown: insomnia.

Nervous system disorders:
Frequency unknown: headache.

Vascular disorders:
Frequency unknown: flushing.

Gastrointestinal disorders:
Frequency unknown: abdominal pain and cramps, stomach upset, bloating, flatulence, indigestion, nausea, vomiting, diarrhoea, constipation.

General disorders and administration site conditions:
Frequency unknown: fever.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of PLUS™ is important. It allows continued monitoring of the benefit/risk balance of PLUS ™. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "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:

Dioscorea villosa L. (Wild Yam) contains diosgenin which have hormonal effects. Diosgenin is metabolised in the liver and eliminated via the bile.

Glycine is an amino acid with antioxidant properties and is involved in muscle protein synthesis. It is rapidly absorbed in the blood and is eliminated within hours after ingestion.

L-Glutamic acid is a source of an amino acid involved in muscle protein synthesis and can have immune boosting effects. It is absorbed in the jejunum, primarily oxidised and a small portion is used for gluconeogenesis.

L-Lysine is a source of an essential amino acid involved in muscle protein synthesis and for the maintenance of good health. L-Lysine may also help in collagen formation. It is catabolised in the liver, leading to acetyl-CoA and is excreted in the faeces and the urine.

L-Arginine is an amino acid involved in muscle protein synthesis. It has antioxidant, hormonal and immunological effects. It has an oral bioavailability of 68 %, is broken down into nitric oxide and L-citrulline and has an elimination half-life of approximately 80 minutes.

Beta-sitosterol is a plant sterol that helps support the functioning of the immune system. It also has hormonal and lipid-lowering properties. Beta-sitosterol is absorbed after oral intake and is excreted in bile and faeces.

Boron is a trace mineral that is a factor in the maintenance of good health. It is well-absorbed from the gastrointestinal tract and is excreted unchanged in the urine, with a half-life of 21 hours.

Larch Arabinogalactan has immune-boosting properties. It is resistant to digestion in the stomach and small intestine and is instead fermented by human colonic microflora to produce acetate, butyrate and propionate.

When ingested, the bulk of tragacanth stretches the intestinal wall, increasing peristalsis. It increases stool weight and decreases gastrointestinal (GI) transit time.

Aloe vera (L.) Burm.f. (Aloe) has anti-inflammatory, antioxidant, detoxification and immune-boosting properties.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Croscarmellose sodium (E468)
Magnesium stearate (E572)
Microcrystalline cellulose (E460)
Silicon dioxide (E551)
Spectrablend™ CC [containing hydroxypropyl methylcellulose (E464), calcium carbonate (E170), medium chain triglyceride (MCT) and xylitol (E967)]
Stearic acid (E570).

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 flip-cap containing 90 tablets and a silica gel dessicant pack.

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

February 2024.

MANNATECH®