Professional Information for IMUNIVAR™

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

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

SCHEDULING STATUS

S0

1. NAME OF THE MEDICINE

IMUNIVAR™ capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Fucoidan 100 mg

from *Undaria pinnatifida* (Mekabu) [sporophyll (leaf and spore), 12:1]

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

White capsule containing an off-white to brown powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

IMUNIVAR™ supports the immune system function.

4.2 Posology and method of administration

Posology:

Adults:

Take 1 capsule daily, or as recommended by a healthcare provider.

Method of administration:

For oral administration.

Do not exceed the recommended dosage.

4.3 Contraindications

Hypersensitivity to *Undaria pinnatifida* (Mekabu) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Bleeding disorders:

IMUNIVAR™ decreases platelet aggregation and may increase the risk of bleeding (see section 4.5). Patients should be advised to discontinue IMUNIVAR™ at least 2 weeks prior to any surgical procedures.

4.5 Interaction with other medicines and other forms of interaction

Anticoagulant or antiplatelet medicines:

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

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

IMUNIVAR™ is unlikely to affect the ability to drive and use machines.

4.8 Undesirable effects

IMUNIVAR™ is generally well-tolerated.

Gastrointestinal disorders:

Less frequent: diarrhoea.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of IMUNIVAR™ is important. It allows continued monitoring of the benefit/risk balance of IMUNIVAR™. Healthcare 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

See section 4.8.

In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

Category and class: D 34.10 Saccharides

Fucoidan is a sulfated polysaccharide extracted from an edible brown algae, *Undaria pinnatifida*.

It inhibits viral replication and stimulates the immune defense functions of the body.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Vegetable capsule (containing hydroxypropyl methylcellulose).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

Store at or below 25 °C.

6.4 Special precautions for storage

Store in a dry place.

Keep in outer container until required for use.

6.5 Nature and contents of container

Silver aluminium blister strips containing 10 capsules packed in an outer carton.

Pack size: 30 capsules.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Lamicare Health

Unit A2, Arden Grove Business Park

Cnr. Omuramba Rd & Racecourse Rd

Milnerton, Cape Town

7441

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

Will be allocated by SAHPRA upon registration.