PROFESSIONAL INFORMATION

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

1. NAME OF THE MEDICINE: NUSERA

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet Serving Size

Servings Per Container: 30 pack size 30 Calories 5q Total Carbohydrate 2 g Sugar Alcohol 1 g Milk Protein Hydrolysate 150 mg

Other Ingredients: Sorbitol, fructose, milk protein hydrolysate (milk), natural flavours, organic cocoa powder (processed with alkali), stearic acid (vegetable), silica, and guar gum. Contains: Milk.

For full list of excipients, see section 6.1

This product is non-GMO and gluten-free.

3. PHARMACEUTICAL FORM

Light brown speckled tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

NuSera is formulated in a great-tasting, chocolate flavoured chewable to help promote a feeling of calmness and relaxation during times of stress. *

* This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use. NuSera does not intend to prevent or cure any form of illness or disease and should not replace any medication. If you suffer from a chronic medical condition, consult your healthcare practitioner before using this product.

4.2 Posology and method of administration

Chew one tablet during times of stress or as directed by your healthcare provider. Do not exceed two tablets per day.

4.3 Contraindications

Do not use if pregnant or nursing.

4.4 Special warnings and precautions for use

Excessive consumption may cause drowsiness. If taking medication, consult your healthcare practitioner before use. Avoid use if taking benzodiazepine or consuming alcohol. Keep out of the reach of children.

4.5 Interaction with other medicines and other forms of interaction

4.6 Fertility, pregnancy and lactation

Do not use if pregnant or nursing.

4.7 Effects on ability to drive and use machines

There are no adequate data from the use of NuSera on the ability to drive and use machines.

4.8 Undesirable effects

4.9 Overdose

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties Category of medicine: D (Complementary Medicine) Class of medicine: 34.13 Health supplements - Other

5.2 Pharmacokinetic properties Pharmacokinetic studies have not been conducted on NuSera product

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol

Fructose Natural flavors

Organic cocoa powder (processed with alkali)

Stearic acid (vegetable)

Guar gum

6.2 Incompatibilities

6.3 Shelf Life

24 Months. 6.4 Special precautions for storage

Keep tightly closed in a cool, dry place.

Keep tablets in original container until required for use

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

Packs of 30 tablets in amber glass bottles

Pack-size: 30 tablets.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Amipro Advanced Development Products (pty) Ltd

Unit 3 Eastgate Business Park, 1 South Road, Marlboro, Sandton, Johannesburg 2063

Tel: 011 802 8101

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.