

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Health Supplement

34.13 Other

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

NUSERA[®], 30 Tablets

COMPOSITION

Each one (1) tablet of NUSERA[®] contain the following actives:

Milk Protein Hydrolysate 150 mg

Inactive Ingredients: Guar gum, natural flavours, organic cocoa powder (processed with alkali), stearic acid (vegetable) and silica.

Contains Sugar: Fructose 0.457 g, sorbitol 1 g.

This product is gluten free and is non-GMO.

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

NUSERA[®] is formulated in a great-tasting, chocolate flavoured chewable to support a healthy lifestyle.

Ingredients	Use for Ingredients
Milk Protein Hydrolysate	Provide a quick release of amino acids to support muscle growth.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take NUSERA[®] if you are hypersensitive (allergic) to any of the ingredients. If you have allergies, be sure to check with your healthcare professional before taking this supplement.

INTERACTIONS

Always tell your healthcare professional if you are taking any other medicine. It is possible that exposure of certain supplement ingredients may interfere with certain medications. (See **Warnings & Special precautions**)

DOSAGE AND DIRECTIONS FOR USE

Adults: Chew one (1) tablet daily or as directed by your healthcare practitioner. **Do no take more than the recommended dose.**

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT

See side-effects.

Treatment:

Discontinue use and consult your doctor, pharmacist or other healthcare professional for advice.

WARNING AND SPECIAL PRECAUTIONS

Contains lactose/fructose. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take NUSERA[®]. Contains sorbitol which may have a laxative effect. Patients with the rare hereditary condition of sorbitol intolerance should not take NUSERA[®]. Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Lactose intolerance: People with lactose intolerance may experience gastrointestinal discomfort from milk-based protein powders. If you are taking the following medication, please consult with your healthcare professional before taking: Antihypertensive drugs: Casein peptides may lower blood pressure, so taking them with other blood pressure medications could cause dangerously low blood pressure. Quinolone antibiotics: Whey protein may reduce the effectiveness of some antibiotics. Tetracyclines: Whey protein contains calcium, which can attach to tetracyclines in the stomach.



If any of the following happens, stop using NUSERA[®] and tell your doctor or go to the casualty department at your nearest hospital:

- Allergic reactions— rash, itching/swelling (especially of the face/tongue/throat).

These are all very serious effects. If you have them, you may have had a serious reaction to NUSERA[®]. You may need urgent medical attention or hospitalisation.

Side effects that usually do not require medical attention (report to your healthcare professional if they continue):

- Gastrointestinal conditions including stomach pain, bloating, flatulence and nausea.

These are all very serious effects. If you have them, you may have had a serious reaction to NUSERA[®]. You may need urgent medical attention or hospitalisation. Seek advice from a healthcare professional if you have any medical condition. Discontinue use immediately should any adverse reaction occur. Read this leaflet carefully because it contains important information for you. This product is available without a doctor's prescription.

- Keep this leaflet. You may need to read it again.
 - Do not share medication with any other person.
 - Ask your pharmacist if you need more information or advice.
 - You must consult a doctor should your condition worsen or does not improve.
- DO NOT USE THIS PRODUCT:**
- If you are hypersensitive (allergic) to any of the ingredients listed.
 - Do not accept this package if seals are broken.

STORAGE INSTRUCTION

Store in a cool, dark place, below 25 °C.

Protect from direct sunlight and heat.

Store in the original bottle.

Keep the bottle tightly closed.

Replace the protective cap after each use.

Do not use after the expiry date stated on the bottle.

Do not use NUSERA[®] if you notice visible signs of deterioration.

IDENTIFICATION

Light brown, round speckled tablet.

PRESENTATION

A white 175 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

SIDE EFFECTS

Should your general health worsen, or if you experience any untoward effects while being exposed to this product, please consult your doctor, pharmacist or other healthcare professional for advice.

REGISTRATION NUMBER - To be allocated by SAHPRA upon registration.

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

NAME AND BUSINESS ADDRESS OF APPLICANT

Distributed by:

Amipro Advanced Development Products (Pty) Ltd
Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension,
Sandton, 2146, Tel: 011-802-8101

DATE OF PUBLICATION

To be allocated by the regulatory authority.

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PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: **S0**

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.13 Ander

HANDELSNAAM EN DOSEERVORM,

NUSERA® , 30 Tablette

SAMESTELING

Elke een (1) tablet van NUSERA® bevat die volgende aktiewe stowwe:

Melk proteien hidrolisaat 150 mg

Onaktiewe bestanddele: Guargom, natuurlike geure, organiese kakaopoer (verwerk met alkali), steariensuur (groente) en silika.

Bevat suiker: Fruktose 0,457 g, sorbitol 1 g.

Hierdie produk is glutenvry en is nie-GGO.

FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

NUSERA® is geformuleer in 'n heerlike, sjokolade-geurende koubaar om 'n gesonde leefstyl te ondersteun.

Bestanddele	Gebruik vir bestanddele
Melk proteien hidrolisaat	Voorsien 'n vinnige vrystelling van aminosure om spiergroei te ondersteun.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **NUSERA®** neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan voordat jy hierdie aanvulling neem.

INTERAKSIES

Vertel altyd jou gesondheidsorgpraktisyn as jy enige ander medisyne gebruik. Dit is moontlik dat blootstelling van sekere aanvullingsbestanddele met sekere medisyne 'n interaksie mag hê. (Sien **Waarskuwings en Spesiale voorsorgmaatreëls**)

DOSIS EN AANWYSINGS VIR GEBRUIK

Volwassenes: Kou daaglik een (1) tablet of soos voorgeskryf deur jou gesondheidspraktisyn.

Moenie meer as die aanbevole dosis neem nie.

DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.

WAARSKUWING EN SPESIALE VOORSORGMATREËLS

Bevat laktose / fruktose. Pasiënte met die seldsame oorerflikke toestande van galaktose-intoleransie, bv. galaktose-intoleransie, Lapp-laktase-tekort, glukose-galaktose-wanabsorpsie of fruktose-intoleransie, moet nie **NUSERA®** neem nie. Bevat sorbitol wat 'n lakseermiddel kan hê. Pasiënte met die seldsame oorerflikke toestand van sorbitol-onverdraagsaamheid moet nie **NUSERA®** neem nie. Indien jy enige van die volgende gedagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Laktose-intoleransie: Mense met laktose-intoleransie kan gastro-intestinale ongemak ervaar van melk-gebaseerde proteïenpoeiers. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: Antihypertensiewe middels: Kaseïenpeptiede kan bloeddruk verlaag, so neem dit saam met ander bloeddrukmedikasie kan gevaarlik lae bloeddruk veroorsaak, Kinolonantibiotika: Wei-proteïene kan die doeltreffendheid van sommige antibiotika verminder, Tetrasiklene: Wei-proteïene bevat kalsium, wat aan tetrasiklene in die maag kan heg. As enige van die volgende gebeur, hou op om **NUSERA®** te gebruik en vertel jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Allergiese reaksies- uitslag, jeuk / swelling (veral van die gesig / tong / keel);

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op **NUSERA®** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê. Nieuwe-efekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan jou gesondheidsorgpraktisyn as hulle voortduur):

- Gastro-intestinale toestande, insluitend maagpyn, opgeblasenheid, windigerheid en naarheid.

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **NUSERA®** gehad. Miskien het u dringende mediese hulp of hospitalisasie nodig.

Raadpleeg 'n gesondheidsorgpraktisyn as u enige mediese toestand het. Staak gebruik onmiddellik indien enige nadelige reaksie plaasvind. Lees hierdie inligtingsblad aandagtig deur, want dit bevat belangrike inligting vir u. Hierdie produk is beskikbaar sonder doktersvoorskrif.

- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
 - Moenie medisyne met enige ander persoon deel nie.
 - Vra jou apteker of jy meer inligting of advies benodig.
 - Jy moet 'n dokter raadpleeg indien jou toestand vererger of nie verbeter nie.
- MOENIE HIERDIE PRODUK GEBRUIK NIE:**
- As jy hipersensitief (allergies) is vir enige van die bestanddele wat gelys word.
 - Jy moet nie hierdie produk aanvaar as seëls gebreek word nie.

NEWE-EFFEKTE

Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie medisyne, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir raad. As jy enige nuwe-efekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE

BEHANDELING DAARVAN Sien nuwe-efekte.

Behandeling: Staak gebruik en raadpleeg jou dokter, apteker of ander gesondheidsorgpraktisyn vir advies.

BERGING INSTRUKSIE

Bêre in 'n koel, donker plek, onder 25 °C.

Beskerm teen direkte sonlig en hitte.

Bêre n die oorspronklike bottel.

Hou die bottel styf toe.

Vervang die beskermende dop na elke gebruik.

Moet nie gebruik word na die vervaldatum wat op die bottel aangedui word nie.

Moenie **NUSERA®** gebruik as u sigbare tekens van agteruitgang opmerk nie.

IDENTIFIKASIE

Ligbruin, ronde gespikkelde tablet.

AANBIEDING

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksieseël, peuterkrimpseël, spons en silikagelsakkie.

REGISTRASIE NOMMER

Om by registrasie deur SAHPRA toegeken te word.

Hierdie medisyne is nie deur SAHPRA geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

NAAM EN BESIGHEIDSADRES VAN APPLIKANT

Versprei deur:

Amipro Advanced Development Products (Pty) Ltd

Unit 3, Eastgate Business Park, 1 South Road,

Eastgate Extension, Sandton, 2146,

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