

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

Category D: Complementary medicine.

Discipline: Health Supplement

34.13 Other

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

NUSERA®, 30 Tablets

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU

- **NUSERA®** is available without a doctor's prescription.
- Nevertheless, you still need to use **NUSERA®** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **NUSERA®** with any other person.
- Ask your pharmacist or healthcare professional if you need more information or advice.

WHAT IS IN THIS LEAFLET

- What **NUSERA®** is and what it is used for.
- What you need to know before you take **NUSERA®**.
- How to take **NUSERA®**.
- Possible side effects.
- How to store **NUSERA®**.
- Contents of the pack and other information.

WHAT NUSERA® CONTAINS

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.

WHAT NUSERA® IS AND WHAT IT IS USED FOR

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

BEFORE YOU TAKE NUSERA®

If you are taking any chronic medication, do not use this product without consulting your healthcare provider. 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.

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

IMPORTANT INFORMATION ABOUT SOME OF THE INGREDIENTS OF NUSERA®

NUSERA® contains fructose. Patients with the rare hereditary conditions of fructose or lactose intolerance should not take **NUSERA®**. Contains sorbitol which may have a laxative effect. **NUSERA®** contains fructose and sorbitol. If you have been told that you have an intolerance to some sugars, you should not take **NUSERA®**.

PREGNANCY AND BREASTFEEDING

Although safety during pregnancy and breastfeeding has been established, consult with your healthcare professional before use. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult with your healthcare professional before taking this supplement.

DRIVING AND USING MACHINES

It is not always possible to predict to what extent **NUSERA®** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in activities relating to requiring mental alertness, judgement and/or sound co-ordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment, until they are aware of the measure to which **NUSERA®** may affect you.

TAKING OTHER MEDICINES WITH NUSERA®

Complementary medicine products contain ingredients which may interact with some medication. If you are taking any chronic medication, do not use this product without consulting your medical practitioner.

Directions for use:

Adults: Chew one (1) tablet daily or as directed by your healthcare practitioner. **Do not take more than the recommended dose.**

IF YOU TAKE MORE NUSERA® THAN YOU SHOULD

In the event of overdose, consult your doctor, pharmacist. Should none of these be available, contact the nearest hospital or poison control centre.

IF YOU FORGET TO TAKE NUSERA®

Do not take a double dose to make up for a missed dose.



HOW TO TAKE NUSERA®

Do not share medicines prescribed for you with any other person. Always take **NUSERA®** exactly as described in this leaflet, or as your doctor, healthcare provider has instructed you. You should check with your doctor, pharmacist or healthcare provider if you are unsure.

POSSIBLE SIDE EFFECTS

NUSERA® may have side effects.

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 practitioner 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, itching:

- 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.

Not all side effects and interactions reported for **NUSERA®** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or healthcare professional.

REPORTING OF SIDE EFFECTS

If you experience side effects, talk to your doctor, pharmacist or other healthcare professional. You can also report side effects to SAHPRA via "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **NUSERA®**.

STORAGE AND DISPOSING OF NUSERA®

Store all medicines out of the reach of children.

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

Protect from direct sunlight and heat.

Store in the original packaging.

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

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

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF NUSERA®

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

IDENTIFICATION OF NUSERA®

Light brown, round speckled tablet.

REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

THIS LEAFLET WAS LAST REVISED ON

10 January 2025

NAME AND ADDRESS OF REGISTRATION HOLDER

Distributed by:

Amipro Advanced Development Products (Pty) Ltd
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PASIËNT INLIGTINGSBLAD

SKEDULERINGSSTATUS S0

Kategorie D: Komplementêre medisyne.

Disipliene: Gesondheidsaanvulling

34.13 Ander

HANDELSNAAM EN DOSEERVORM,

NUSERA[®], 30 Tablette

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT

BELANGRIKE INLIGTING VIR U

- **NUSERA[®]** is beskikbaar sonder doktersvoorskrif.
- U moet steeds **NUSERA[®]** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie **NUSERA[®]** met enige ander persoon deel nie.
- Vra jou apteker of gesondheidsorgpraktisyn of jy meer inligting of advies benodig.

WAT IS IN HIERDIE INLIGTINGSBLAD

- Wat **NUSERA[®]** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **NUSERA[®]** neem.
- Hoe om **NUSERA[®]** te neem.
- Moontlike newe-effekte.
- Hoe om **NUSERA[®]** te bêre.
- Inhoud van die pak en ander inligting

WATTER NUSERA[®] BEVAT

Elke een (1) tablet **NUSERA[®]** bevat die volgende aktiewe:

Melk proteïen hidrolisaat 150 mg

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

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

Hierdie produk is glutenvry en is nie-GGO.

WAT IS NUSERA[®] KAPSULES EN WAARVOOR WORD DIT GEBRUIK

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

VOORDAT JY NUSERA[®] NEEM

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 allergies het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan voordat jy hierdie aanvulling neem.

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

BESTUUR EN GEBRUIK VAN MASIËNE

Dit is nie altyd moontlik om te voorspel in watter mate **NUSERA[®]** die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. Pasiënte moet seker maak dat hulle nie betrokke raak by aktiwiteite wat verband hou met die vereiste van verstandelike waaksaamheid, oordeel en/of gesonde koördinasie en visie nie, byvoorbeeld bestuur, ry, vlieg, seil, bedryfsmasjien/toerusting, totdat hulle bewus is van die mate waartoe **NUSERA[®]** jou beïnvloed.

NEEM VAN ANDER MEDISYNE SAAM MET NUSERA[®]

Komplementêre medisyne produkte bevat bestanddele wat met sommige medisyne 'n interaksie kan hê. As jy enige chroniese medisyne gebruik, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie.

SWANGERSKAP EN BORSVOEDING

Alhoewel veiligheid tydens swangerskap en borsvoeding vasgestel is, raadpleeg u gesondheidsorgpraktisyn voor gebruik. As u swanger is of borsvoed, dink dat u swanger is of beplan om 'n baba te hê, raadpleeg u gesondheidsorgpraktisyn voordat u hierdie aanvulling neem.

BELANGRIKE INLIGTING OOR SOMMIGE VAN DIE BESTANDELE VAN NUSERA[®]

NUSERA[®] bevat fruktose. Pasiënte met die seldsame oorerflike toestand van fruktose of laktose-intoleransie moet nie **NUSERA[®]** neem nie. Bevat sorbitol wat 'n lakseermiddel kan hê. **NUSERA[®]** bevat fruktose en sorbitol. As daar vir jou gesê is dat jy 'n onverdraagsaamheid teenoor sommige suikers het, moet jy nie **NUSERA[®]** neem nie.

HOE OM NUSERA[®] TE NEEM

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **NUSERA[®]** presies soos beskryf in hierdie inligtingsblad, of soos u dokter, gesondheidsorgpraktisyn voorgeskryf het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisyn as jy onseker is.

Aanwysings vir gebruik:

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

Moenie meer as die aanbevole dosis neem nie.

AS JY MEER NUSERA[®] NEEM AS WAT JY MOET

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een hiervan beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

AS JY VERGEET OM NUSERA[®] TE NEEM

Moenie 'n dubbele dosis neem om op te maak vir 'n dosis wat oorgeslaan is nie.

MOONTLIKE NEWE-EFFEKTE

NUSERA[®] kan newe-effekte hê.

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Laktose-intoleransie: Mensse met laktose-intoleransie kan gastro-intestinale ongemak ervaar van melk-gebaseerde proteïenpoëiers. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: Antihipertensiewe middels: Kaseleneptiede 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, Tetrasielene: Wei-proteïene bevat kalsium, wat aan tetrasielene in die maag kan heg. As u een 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 mag dalk dringende mediese hulp of hospitalisasie nodig hê.

Nuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteur aan u gesondheidsorgpraktisyn as dit voortduur):

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

Nie alle newe-effekte en interaksies wat vir **NUSERA[®]** gerapporteer word, is by hierdie inligtingsblad ingesluit nie. 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 newe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

AANMELDING VAN NEWE-EFFEKTE

As jy newe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisyn. U kan ook newe-effekte aan SAHPRA rapporteer via "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies:

<https://www.sahpra.org.za/Publications/Index/8>. Deur newe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **NUSERA[®]**.

HOE OM NUSERA[®] TE BÊRE

Bêre alle medisyne buite bereik van kinders.

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

Beskermt teen direkte sonlig en hitte.

Bêre in die oorspronklike verpakking.

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.

Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

AANBIEDING VAN NUSERA[®]

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

IDENTIFIKASIE VAN NUSERA[®]

Ligbruin, ronde gespikkelde tablet.

REGISTRASIONOMMER

Om deur SAHPRA toegeen te word by registrasie.

TOEGANG TOT DIE OOREENSTEMMende PROFESSIONELE INLIGTING

Skandeer QR-kode.

HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP

10 Januarie 2025

NAAM EN ADRES VAN REGISTRASIEHOUDER

Versprei deur:

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