

PROFESSIONAL INFORMATION

SCHEDULING STATUS:

Not scheduled.

PROPRIETARY NAME AND DOSAGE FORM:



USN DIGEST X PROBIOTIC

(vegi capsules)

COMPOSITION:

Active ingredients:

EACH CAPSULE CONTAINS:

Bifidobacterium lactis B420™ (HOWARU® Shape)
Inulin 92 % (Orafti® Synergy 1)

Per Capsule

10 billion CFU
250 mg

CFU = Colony Forming Units

Contains Sugar (Glucose, Fructose & Sucrose 20 mg)

Other ingredients: Magnesium stearate, microcrystalline cellulose, silicon dioxide, vegi capsules.

CATEGORY AND CLASS:

D 34.12 Multiple Substance Formulation

PHARMACOLOGICAL ACTION:

HOWARU® Shape: HOWARU® Shape is a unique formula of 10 billion CFU *Bifidobacterium lactis* B420™. *Bifidobacterium lactis* B420™ is a naturally occurring strain, originally isolated from dairy products. The strain's effect on metabolic health and the gut barrier function has been studied for more than a decade. In a recent study, the strain was found to increase the relative abundance of *Akkermansia muciniphila* in the gut microbiota – a bacterium linked with improved metabolic health, which means the risk of weight-related health issues may be reduced by helping control body fat mass. HOWARU® Shape does not contain stimulants, is effective and well-tolerated.

Inulin 92 % (Orafti® Synergy 1): Inulin prebiotic may help to improve the balance of the intestinal flora by stimulating beneficial *bifidobacterial* growth – an important element of good digestive health. It has also shown to support weight management by blood glucose control and reducing appetite. Inulin's effects on body weight are thought to be due to increased expression of glucagon-like peptide 1 (GLP-1) and reduced plasma ghrelin levels. Increased expression and secretion of GLP-1 can lead to delayed gastric emptying and increased feelings of satiety. Orafti® Synergy 1 may also increase calcium absorption for stronger bones.

INDICATIONS:

USN DIGEST X PROBIOTIC is indicated as an aid to a weight management programme by supporting healthy microflora associated with metabolic health, combined with a balanced, energy-restricted diet and regular exercise.

CONTRAINDICATIONS:

This product is contraindicated for individuals that are hypersensitive (allergic) to any of the listed ingredients.

Not for use in persons under the age of 18 years.

WARNINGS AND SPECIAL PRECAUTIONS:

- **Immunodeficiency:** There is some concern that probiotics might grow too well in people who are immunocompromised and might cause infections. If you have a weakened immune system (e.g. you have HIV/AIDS or are undergoing cancer treatment), consult your health care professional before using *bifidobacteria*.
- **Diarrhea:** Do not use **USN DIGEST X PROBIOTIC** if you have diarrhea lasting more than 2 days (especially if you also have a high fever).
- **Vaginal or urinary tract infections:** If you suffer from recurrent vaginal or urinary tract infections, consult your health care professional before using **USN DIGEST X PROBIOTIC**.
- Do not exceed the daily recommended dose.

INTERACTIONS:

- **Antibiotics:** Taking antibiotics along with *bifidobacteria* might reduce the effectiveness of **USN DIGEST X PROBIOTIC**. To avoid this interaction, take **USN DIGEST X PROBIOTIC** at least two hours before or after taking antibiotics.
- **Antidiabetic medicine:** Inulin might decrease blood glucose levels and have additive effects when used concomitantly with antidiabetic medicine (such as metformin, glimepiride, insulin, and others). Use with caution.
- **Herbs and supplements with hypoglycaemic potential:** Herbs and supplements with hypoglycaemic potential (such as fenugreek, garlic, Panax ginseng and others) can have additive blood glucose lowering effects when used with **USN DIGEST X PROBIOTIC**.

HUMAN REPRODUCTION:

USN DIGEST X PROBIOTIC is possibly safe during pregnancy and lactation. However, there are insufficient reliable information available. Please consult your health care practitioner before use.

DOSAGE AND DIRECTIONS FOR USE:

Adults: As a nutritional supplement, take 1 vegi capsule daily with water. Can be used with any **USN® PHEDRACUT** product.

Do not exceed the recommended daily dosage.

SIDE EFFECTS:

The following side effects may be associated with the use of **USN DIGEST X PROBIOTIC**:

- **Immune system disorders:** *Frequency unknown* – Hypersensitivity and/or allergic reactions.
- **Endocrine disorders:** *Frequency unknown* – Hypoglycaemia.
- **Gastrointestinal disorders:** *Frequency unknown* – Abdominal cramps, bloating, flatulence, diarrhea, decreased appetite.

Should your general health worsen, or if you experience any untoward effects or allergic reactions while taking this medicine, please consult your doctor, pharmacist or other healthcare professional immediately.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

None known. If suspected overdose occurs, please consult your healthcare practitioner immediately. Treatment should be symptomatic and supportive.

IDENTIFICATION:

White vegi capsules containing white powder.

PRESENTATION:

White PET plastic container with a white USN lid, containing 30 capsules, packed inside a carton.

STORAGE INSTRUCTIONS:

Store in a cool, dry place at or below 25 °C.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

To be allocated by the Authority.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

USN Pty (Ltd)
Building C, Southdowns Office Park, 2nd Floor,
21 Karee Street, Irene Ext 54, 0157
Tel: 0861 111 876

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:


January 2020.

COMPLEMENTARY MEDICINE:

Health Supplement: Multiple Substance Formulation.

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

PHE079/PI-PI/L/A

JOB: SACE_Digest X Probiotic_30s	SIZE: 300mm x 315mm
STOCK: Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>	
COLOURS:  K	FINISHING: <input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Doming <input type="checkbox"/> Embossing

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:
Not scheduled.

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:



USN DIGEST X PROBIOTIC

(vegi capsules)

Read all of this leaflet carefully because it contains important information for you.

USN DIGEST X PROBIOTIC is available without a doctor's prescription. Nevertheless, you still need to use **USN DIGEST X PROBIOTIC** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **USN DIGEST X PROBIOTIC** with any other person.
- Ask your pharmacist if you need more information or advice.

1. WHAT USN DIGEST X PROBIOTIC:

Active ingredients:

EACH CAPSULE CONTAINS:

Bifidobacterium lactis B420™ (HOWARU® Shape)

Inulin 92 % (Oralt® Synergy 1)

CFU = Colony Forming Units

Contains Sugar (Glucose, Fructose & Sucrose 20 mg)

Other ingredients: Magnesium stearate, microcrystalline cellulose, silicon dioxide, vegi capsules.

2. WHAT USN DIGEST X PROBIOTIC IS USED FOR:

USN DIGEST X PROBIOTIC is indicated as an aid to a weight management programme by supporting healthy microflora associated with metabolic health, combined with a balanced, energy-restricted diet and regular exercise.

3. BEFORE YOU TAKE USN DIGEST X PROBIOTIC:

Do not take USN DIGEST X PROBIOTIC:

- If you are hypersensitive (allergic) to any of the active or inactive ingredients (see **WHAT USN DIGEST X PROBIOTIC CONTAINS**).
- If you are under 18 years of age.

Take special care with USN DIGEST X PROBIOTIC:

- If you have a weakened immune system (e.g. if you have HIV/AIDS or are undergoing cancer treatment). There is some concern that probiotics might grow too well in people who are immunocompromised and might cause infections. Consult your health care professional before using **USN DIGEST X PROBIOTIC**.
- If you have diarrhea (especially if you also have a high fever) lasting more than 2 days. Use with caution.
- If you suffer from recurrent vaginal or urinary tract infections. Consult your health care professional before using **USN DIGEST X PROBIOTIC**.
- Do not exceed the daily recommended dose.

Taking USN DIGEST X PROBIOTIC with food and drink:

- **USN DIGEST X PROBIOTIC** can be taken with or without meals.

Pregnancy and Breastfeeding:

- **USN DIGEST X PROBIOTIC** is possibly safe during pregnancy and lactation. However, there are insufficient reliable information available. Please consult your health care practitioner before use.

Driving and using machinery:

It is unlikely that **USN DIGEST X PROBIOTIC** will affect your ability to drive a vehicle or operate machinery requiring your attention.

Taking other medicines with USN DIGEST X PROBIOTIC:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines).

If you are on any of the following medicine or treatment, you should discuss the use of **USN DIGEST X PROBIOTIC** with your doctor or pharmacist first:

- Antibiotics (such as amoxicillin, cefalexin, tetracycline, tobramycin, etc.). Use of these medicines with *bifidobacteria* might reduce the effectiveness of **USN DIGEST X PROBIOTIC**. To avoid this interaction, take **USN DIGEST X PROBIOTIC** at least two hours before or after taking antibiotics.
- Antidiabetic medicine (such as metformin, glimepiride, insulin, etc.). Inulin might decrease blood glucose levels and have additive effects when used with antidiabetic medicine. Use with caution.
- Herbs and supplements with hypoglycaemic potential (such as fenugreek, garlic, Panax ginseng and others), as these supplements can increase the risk of low blood sugar when used with **USN DIGEST X PROBIOTIC**.

4. HOW TO TAKE USN DIGEST X PROBIOTIC:

Do not share medicines prescribed for you with any other person.

Always take **USN DIGEST X PROBIOTIC** exactly as directed.

You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

- **Adults:** As a nutritional supplement, take 1 vegi capsule daily with water. Can be used with any **USN® PHEDRACUT** product.

Do not exceed the recommended daily dosage.

If you take more USN DIGEST X PROBIOTIC than you should:

In the event of over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take USN DIGEST X PROBIOTIC:

Take the missed dose as soon as you remember. If it is almost time for your next dose, do not take the missed dose but simply take your next dose at the normal time.

Do not take a double dose to make up the one you missed.

5. POSSIBLE SIDE EFFECTS:

- **USN DIGEST X PROBIOTIC** can have side effects.
- Not all side effects reported for **USN DIGEST X PROBIOTIC** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your health care provider for advice.
- If any of the following happens, stop taking **USN DIGEST X PROBIOTIC** and tell your doctor immediately or go to the casualty department at your nearest hospital:
 - Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
 - Rash or itching.
 - Fainting.

PASIËNTINLIGTINGSBLAADJIE

SKEDULERINGSTATUS:

Nie geskeduleer nie.

HANDELSNAAM, STERKTE EN FARMASEUTIESE VORM:



USN DIGEST X PROBIOTIC

(vegikapsules)

Lees die hele pamflet noukeurig deur, aangesien dit belangrike inligting vir u bevat.

USN DIGEST X PROBIOTIC is beskikbaar sonder 'n dokter se voorskrif. Nietemin moet u steeds **USN DIGEST X PROBIOTIC** versigtig gebruik om die beste resultate te verkry.

- Bewaar hierdie pamflet. U mag dit dalk weer moet lees.
- Moenie **USN DIGEST X PROBIOTIC** met enige ander persoon deel nie.
- Vra u apteker indien u verdere inligting of advies benodig.

1. WAT USN DIGEST X PROBIOTIC BEVAT:

Aktiewe bestanddele:

ELKE KAPSULE BEVAT:

Bifidobacterium lactis B420™ (HOWARU® Shape)

Inulien 92 % (Oralt® Synergy 1)

KVE = Kolonievormende Eenhede

Bevat Suiker (Glukose, Fruktose & Sukrose 20 mg)

Ander bestanddele: Magnesiumstearaat, mikrokristallyne sellulose, silikondioksied, vegikapsules.

2. WAARVOOR USN DIGEST X PROBIOTIC GEBRUIK WORD:

USN DIGEST X PROBIOTIC word aangedui as 'n hulpmiddel in 'n gewigsbeheerprogram deur die ondersteuning van gesonde mikroflora wat met metaboliese gesondheid verband hou, gekombineer met 'n gebalanseerde, energiebeperkte dieet en gereelde oefening.

3. VOOR U USN DIGEST X PROBIOTIC NEEM:

Moenie USN DIGEST X PROBIOTIC neem:

- Indien u hipersensitief (allergies) is vir enige van die aktiewe of onaktiewe bestanddele (sien **WAT USN DIGEST X PROBIOTIC BEVAT**).
- Indien u jonger as 18 jaar is.

Neem spesiale sorg met USN DIGEST X PROBIOTIC:

- Indien u 'n verswakte immuunstelsel het (bv. indien u MIV/vigs het of kankerbehandeling ondergaan). Daar is kommer dat probiotika te goed kan groei by mense wie 'n verswakte immuunstelsel het en infeksies kan veroorsaak. Raadpleeg u gesondheidsorgdeskundige voor die gebruik van **USN DIGEST X PROBIOTIC**.
- Indien u diaree het (veral as u 'n hoë koors ook het) wat langer as 2 dae duur. Gebruik met omsigtigheid.
- Indien u ly aan herhalende vaginale of urieneweginfeksies. Raadpleeg u gesondheidsorgdeskundige voor die gebruik van **USN DIGEST X PROBIOTIC**.
- Moenie die voorgeskrewe daaglikse dosering oorskry nie.

Neem van USN DIGEST X PROBIOTIC met voedsel en drank:

- **USN DIGEST X PROBIOTIC** kan met of sonder maaltye geneem word.

Swangerskap en Borsvoeding:

- **USN DIGEST X PROBIOTIC** is moontlik veilig gedurende swangerskap en borsvoeding. Daar is egter onvoldoende betroubare inligting beskikbaar. Raadpleeg asseblief u gesondheidsorgpraktisyn voor gebruik.

Bestuur en gebruik van masjienerie:

Dit is onwaarskynlik dat **USN DIGEST X PROBIOTIC** u vermoë sal beïnvloed om 'n voertuig te bestuur of masjienerie te gebruik wat u aandag verg.

Die neem van ander medikasie saam met USN DIGEST X PROBIOTIC:

Stel altyd u gesondheidsorgdeskundige daarvan in kennis indien u enige ander medikasie gebruik (Dit sluit aanvullende of tradisionele medikasie in).

Indien u enige van die volgende medisyne gebruik of behandeling ondergaan, bespreek eers die gebruik van **USN DIGEST X PROBIOTIC** met u dokter of apteker:

- Antibiotika (soos amoksisillien, kefaleksien, tetrasiklien, tobramisien, ens.) Die gebruik van hierdie medisyne saam met *bifidobakterieë* kan die effektiwiteit van **USN DIGEST X PROBIOTIC** verminder. Om hierdie interaksie te vermy, neem **USN DIGEST X PROBIOTIC** ten minste twee ure voor of na die neem van antibiotika.
- Antidiabetiese medisyne (soos metformien, glimepiried, insulien, ens.). Inulien mag bloedglukosevlakke verlaag en additiewe effekte hê wanneer saam met antidiabetiese medisyne gebruik word. Gebruik met omsigtigheid.
- Kruie en aanvullings met hipoglukemiese potensiaal (soos fenegriek, knoffel, Panax ginseng, ens.), aangesien hierdie aanvullings die risiko van lae bloedsuier kan verhoog indien saam met **USN DIGEST X PROBIOTIC** gebruik word.

4. HOE OM USN DIGEST X PROBIOTIC TE NEEM:

Moenie medikasie wat vir u voorgeskryf is met enige ander persoon deel nie. Neem altyd **USN DIGEST X PROBIOTIC** presies soos voorgeskryf. Raadpleeg u dokter of apteker indien u onseker is.

Die gewone dosering is:

- **Volwassenes:** As 'n dieetaanvulling, neem 1 vegikapsule daaglik met water. Kan saam met enige **USN® PHEDRACUT** produk gebruik word.

Moenie die aanbevole daaglikse dosering oorskry nie.

Indien u meer USN DIGEST X PROBIOTIC neem as wat u veronderstel is:

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

Indien u vergeet om USN DIGEST X PROBIOTIC te neem:

Neem die dosis wat u oorgeslaan het sodra u onthou. Indien dit amper tyd is vir die volgende dosis, moenie die vergete dosis neem nie, maar neem die volgende dosis die normale tyd.

Moenie 'n dubbele dosis neem om op te maak vir die vergete individuele dosis nie.

5. MOONTLIKE NEWE-EFFEKTE:

- **USN DIGEST X PROBIOTIC** kan newe-effekte hê.
- Nie alle newe-effekte van **USN DIGEST X PROBIOTIC** wat aangemeld is, word by hierdie pamflet ingesluit nie. Indien u algemene gesondheid versleg of as u enige ongewenste effekte ervaar terwyl u hierdie medisyne gebruik, raadpleeg u gesondheidsorgdeskundige vir advies.
- Indien enige van die volgende gebeur, staak **USN DIGEST X PROBIOTIC** se gebruik en stel u dokter onmiddellik in kennis of gaan na die ongevalle-afdeling by u naaste hospitaal:
 - Swelling van u hande, voete, enkels, gesig, lippe, mond of keel, wat probleme met sluk of asemhaling mag veroorsaak.
 - Uitslag of jeukerigheid.
 - Flou word.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **USN DIGEST X PROBIOTIC**. You may need urgent medical attention or hospitalisation.

- Tell your doctor as soon as possible if you notice any of the following:
 - Low blood sugar
 - Abdominal cramps
 - Bloating
 - Flatulence (gas)
 - Diarrhea
 - Decreased appetite

- If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF USN DIGEST X PROBIOTIC:

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from light and moisture.
- Do not store in the bathroom.
- Store in its original container.
- Keep the container tightly closed.
- Do not use after the expiry date stated on the container.
- Do not use **USN DIGEST X PROBIOTIC** if you notice visible signs of deterioration.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF USN DIGEST X PROBIOTIC:

White PET plastic container with a white USN lid, containing 30 capsules, packed inside a carton.

8. IDENTIFICATION OF USN DIGEST X PROBIOTIC:

White vegi capsules containing white powder.

9. REGISTRATION NUMBER:

To be allocated by the Authority.

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

USN Pty (Ltd)
Building C, Southdowns Office Park, 2nd Floor,
21 Karee Street, Irene Ext 54, 0157
Tel: 0861 111 876

11. DATE OF PUBLICATION:

January 2020.

12. COMPLEMENTARY MEDICINE:

Health Supplement: Multiple Substance Formulation.

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

Al hierdie newe-effekte is baie ernstig van aard. Indien u hierdie newe-effekte ervaar, het u dalk 'n ernstige allergiese reaksie tot **USN DIGEST X PROBIOTIC** gehad. U mag dringende mediese aandag of hospitalisasie benodig.

- Stel u dokter so gou as moontlik in kennis sou u enige van die volgende opmerk:
 - Lae bloedsuiker
 - Maagkrampe
 - Opgeblaasheid
 - Winderigheid (gas)
 - Diarree
 - Verminderde eetlus

- Indien u enige newe-effekte waarneem wat nie in hierdie pamflet genoem word nie, stel asseblief u dokter of apteker in kennis.

6. BERGING EN WEGDOENING VAN USN DIGEST X PROBIOTIC:

- Bewaar alle medikasie buite bereik van kinders.
- Bewaar teen of benede 25 °C.
- Beskerm teen lig en vog.
- Moenie die produk in die badkamer bewaar nie.
- Bewaar in die oorspronklike houer.
- Hou die houer dig toe.
- Moenie gebruik na die vervaldatum aangedui op die houer nie.
- Moenie **USN DIGEST X PROBIOTIC** gebruik indien u enige sigbare tekens van produkafbraak opmerk nie.

Neem alle ongebruikte medikasie terug na u apteker.

Moenie ongebruikte medikasie in dreine of rioolstelsels (bv. toilette) afspoel nie.

7. AANBEDIING VAN USN DIGEST X PROBIOTIC:

Wit PET-plastiekhouer met 'n wit USN-deksel, wat 30 kapsules bevat, verpak binne 'n karton.

8. IDENTIFIKASIE VAN USN DIGEST X PROBIOTIC:

Wit vegikapsules wat wit poeier bevat.

9. REGISTRASIENOMMER:

Vir toekenning deur die Raad.

10. NAAM EN ADRES VAN REGISTRASIEHOUER:

USN (Edms) Bpk
Gebou C, Southdowns Besigheidspark, 2de Vloer,
Kareestraat 21, Irene Uitbr. 54, 0157
Tel: 0861 111 876


11. DATUM VAN PUBLIKASIE:

Januarie 2020.

12. KOMPLEMENTÊRE MEDISYNE:

Gesondheidsaanvulling: Veelvuldige Bestanddeel Formulasie.

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

JOB: SACE_Digest X Probiotic_30s	SIZE: 300mm x 315mm
STOCK: Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>	
COLOURS:  K	FINISHING: <input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Doming <input type="checkbox"/> Embossing