

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Discipline Specific

33.7 Combination Product



PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

URIDYN[®], 30 Tablets

COMPOSITION

Each one (1) tablet of URIDYN[®] contains the following actives:

D-mannose	500 mg
Cranberry Extract (<i>Vaccinium macrocarpon</i> aiton)	68,5 mg
[Whole plant extract]	
Vitamin C (as ascorbic acid)	45 mg
2'-Fucosyllactose (providing L-fucose 11,7 mg and D-galactose 12,9 mg and D-glucose 12,9 mg)	37,5 mg
Quercetin	25 mg
Decaffeinated Green tea (<i>Camellia sinensis</i> (L.) Kuntze)	7,5 mg
[Leaf extract providing 1 mg Epigallocatechin gallate (EGCG)]	

Inactive Ingredients: Bamboo extract, chicory fibre, hydroxypropylcellulose, magnesium stearate, microcrystalline cellulose, silicon dioxide, stearic acid

This product is suitable for vegetarians, non-GMO, dairy & gluten free (Sugar Free)

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

URIDYN[®] is beneficial for kidney, urinary tract and bladder function.

This formula contains a unique combination of nutrients which supports renal function and maintains a healthy bladder. Regular use may help to maintain optimal urinary tract health.

Ingredient	Uses for ingredient
D-mannose	Supports urinary tract health by preventing bacterial adhesion to the bladder wall.
Cranberry Extract (<i>Vaccinium macrocarpon</i> aiton)	Helps maintain urinary tract health and reduces the recurrence of urinary tract infections (UTIs).
Vitamin C (as ascorbic acid)	Boosts immune function, provides antioxidant support, and aids in collagen synthesis.
2'-Fucosyllactose	Supports gut health by promoting beneficial bacteria and enhancing the gut microbiome balance.
Quercetin	Provides antioxidant and anti-inflammatory support; may help reduce allergy symptoms.
Decaffeinated Green tea (<i>Camellia sinensis</i> (L.) Kuntze)	Offers antioxidant support, promotes cardiovascular health, and supports metabolism.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take URIDYN[®] 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. **Surgery:** URIDYN[®] might increase the risk of bleeding during and after surgery. Stop using URIDYN[®] at least 2 weeks before a scheduled surgery.

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)

DO dosage AND DIRECTIONS FOR USE

Adults:

Acute: Take four (4) tablets in the evening with plenty of water. If there is no relief within 7 days, consult your healthcare practitioner.

Maintenance: Take one (1) tablet in the evening or as directed by your healthcare practitioner.

Do not take more than the recommended dose.

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.

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

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: : Bleeding disorders, Heart disease, Diabetes, Stroke, History of kidney stones, Allergy to lactose. If you are taking the following medication, please consult with your healthcare professional before taking: blood clotting (Anticoagulant / Antiplatelet drugs), Warfarin (Coumadin), Antibiotics (Tetracycline antibiotics), Aspirin (contains salicylic acid), Medications for diabetes (Antidiabetes drugs). May reduce effectiveness of chemotherapy drugs (e.g., bortezomib), May increase iron absorption (caution in hemochromatosis). If any of the following happens, stop using URIDYN[®] 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), severe dizziness, trouble breathing;

These are all very serious effects. If you have them, you may have had a serious reaction to URIDYN[®]. 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):

- Diarrhea, Bloating, Gastrointestinal discomfort.
- These are all very serious effects. If you have them, you may have had a serious reaction to URIDYN[®]. 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 URIDYN[®] if you notice visible signs of deterioration.

IDENTIFICATION

Uncoated, mixed pink and white, oblong tablets.

PRESENTATION

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

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.

PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: 50

Kategorie D: Komplementêre medisyne.

Dissipline: Dissiplinespesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

URIDYN® , 30 Tablette

SAMESTELING

Elke (1) tablet URIDYN® bevat die volgende aktiewe stowwe:	
D-mannose	500 mg
Cranberry Uittreksel (<i>Vaccinium macrocarpon</i> aiton) [Hele plant uittreksel]	68,5 mg
Vitamiën C (as askorbiensuur)	45 mg
2'-Fucosyllactose (verskaf L-fucose 11,7 mg en D-galaktose 12,9 mg en D-glukose 12,9 mg)	37,5 mg
Quercetin	25 mg
Kafeienvrye groen tee (<i>Camellia sinensis</i> (L.) Kuntze) [Blaaerstrak wat 1 mg Epigallocatechin gallate (EGCG) verskaf]	7,5 mg

Onaktiewe bestanddele: Bamboes uittreksel, sigoreivesel, hidroksipropylselulose, magnesiumstearaat, mikrokristallyne selulose, silikondoksied, steariensuur

Hierdie produk is geskik vir vegetariërs, nie-GMO, suiwel- en glutenvry (suikervry)

FARMAKOLOGIESE KLASIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

URIDYN® is voordelig vir nier-, urienweg- en blaasfunksie. Hierdie formule bevat 'n unieke kombinasie van voedingstowwe wat Ondersteun nierfunksie en handhaaf 'n gesonde blaas. Gereelde Gebruik kan help om optimale urienweggesondheid te handhaaf.

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)

DOSES EN AANWYSINGS VIR GEBRUIK

Volwasse:

Akuut: Neem vier (4) tablette in die aand met baie water. As daar binne 7 dae geen verligting is nie, raadpleeg jou gesondheidsorgpraktisyn.

Onderhoud: Neem een (1) tablet in die aand of soos aangedui deur jou gesondheidsorgpraktisyn.

Moenie meer as die aanbevole dosis neem nie.

Bestanddeel	Gebruik vir bestanddeel
D-mannose	Ondersteun urienweggesondheid deur bakteriële adhesie aan die blaaswand te voorkom.
Cranberry Uittreksel (<i>Vaccinium macrocarpon</i> aiton)	Help om urienweggesondheid te handhaaf en verminder die herhaling van urienweginfeksies (UTI's).
Vitamiën C (as askorbiensuur)	Verhoog immuunfunksie, bied antioksidantondersteuning, en help met kollageensintese.
2'-Fucosyllactose	Ondersteun dermgewondheid deur voordelige bakterieë te bevorder en die dermmikrobioom balans te verbeter.
Quercetin	Bied antioksidante en anti-inflammatoriese ondersteuning; kan help om allergie simptome te verminder.
Kafeienvrye groen tee (<i>Camellia sinensis</i> (L.) Kuntze)	Bied antioksidantondersteuning, bevorder kardiovaskulêre gesondheid en ondersteun metabolisme.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **URIDYN®** 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. **Chirurgie:** **URIDYN®** kan die risiko van bloeding tydens en na die operasie verhoog. Hou op om **URIDYN®** ten minste 2 weke voor 'n geskeduleerde operasie te gebruik.

DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.

WAARSKUWING EN SPESIALE VOORSORGMAATREËLS

Indien jy enige van die volgende gedagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Bloedingsversteurings, hartsiektes, diabetes, beroerte, geskiedenis van nierstene, allergie vir laktose. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: bloedstolling (Koagulant / Anti-platelet-middels), Warfarin (Coumadin), Antibiotika (Tetrasielien-antibiotika), Aspirien (bevat salisielsuur), Medisyne vir diabetes (Antidiabetes-medisyne), Kan die doeltreffendheid van chemoterapie-medisyne verminder (bv. Bortezomib), Kan yster verhoog absorpsie (versigtig in hemochromatose). As enige van die volgende gebeur, hou op om **URIDYN®** 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), erge duiseligheid, probleme met asemhaling;

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

- Diarree, opgeblasenheid, ongemak in die spysverteringskanaal. Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **URIDYN®** 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-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

BEKENE SIMPTOME VAN OORDOSEEREN EN BESONDERHEDE VAN DIE

BEHANDELING DAARVAN Sien nuwe-effekte.

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

IDENTIFIKASIE

Onbedekte, gemengde pienk en wit, langwerpige tablette.

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 BESIGHEIDSAADRES VAN APPLIKANT

Versprei deur:

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