Metagenics®

UriDyn®

Professional Information for UriDyn®

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
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1. NAME OF THE MEDICINE
UriDyn® tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains:

D-mannose	500,00 mg
Cranberry extract (Vaccinium macrocarpon Aiton)	68,50 mg
PAC-A	9,00 mg
Vitamin C	45,00 mg
2'-fucosyllactose	37,50 mg
Quercetin	25,00 mg
Green tea leaf extract (Camellia sinensis (L.) Kuntze)	7,50 mg
Epigallocatechin gallate (EGCG)	1,00 mg

Sugar free.
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Tablets.
Uncoated, mixed pink and white, oblong tablet.

4 .CLINICAL PARTICULARS
4.1. Therapeutic indications
UriDyn® is beneficial for kidney, urinary tract and bladder function. This formula contains a unique combination of cranberry extract, D-mannose, quercetin and 2'-fucosyllactose (HMO), as well as green tea, which supports renal function and maintains a healthy bladder. Regular use may help to maintain optimal urinary tract health.

4.2. Posology and method of administration
Adults 18 years and older:
Acute: Take 4 tablets in the evening with plenty of water. If there is no relief within 7 days, consult your healthcare practitioner.
Maintenance: Take 1 tablet in the evening or as directed by your healthcare practitioner.

4.3. Contraindications
- Hypersensitivity to active ingredients or to any of the excipients listed in section 6.1.
- UriDyn® is contra-indicated with Atorvastatin (refer to section 4.5).

4.4. Special warnings and precautions for use
- Large amounts of cranberry could trigger an allergic reaction in people with aspirin allergy or asthma, as it contains significant amounts of salicylic acid.
- Cranberry and vitamin C increase the risk of kidney stones; use with caution in patients with a history of kidney stones.
- Stop use and consult a relevant healthcare provider if you develop symptoms of liver trouble such as yellowing of the skin/eyes (jaundice), stomach pain, dark urine, sweating, nausea, unusual tiredness and/or loss of appetite.
- Consult a health care practitioner prior to use if you have a liver disorder or an iron deficiency.
- Consult a relevant healthcare provider for use beyond 12 weeks.
- Consult a relevant healthcare provider prior to use if you are pregnant or breastfeeding.

4.5. Interaction with other medicines and other forms of interaction
D-mannose:
- No known interactions.

Cranberry:
- Warfarin: Cranberry might increase the levels and adverse effects of warfarin.

Vitamin C:
- Alkylating agents: The antioxidant effects of vitamin C might reduce the effectiveness of alkylating agents.
- Aluminium: Vitamin C can increase the amount of aluminium absorbed from aluminium compounds.
- Antitumour antibiotics: The antioxidant effects of vitamin C might reduce the effectiveness of antitumour antibiotics.
- Estrogen: Vitamin C might increase blood levels of estrogens.
- Levothyroxine: Vitamin C can increase levothyroxine absorption.

2- fucosyllactose:
- No known interactions.

Quercetin:
- Diclofenac: Concomitant use might increase the levels and adverse effects of diclofenac.

Green tea:
- Atorvastatin: Green tea extract seems to reduce the levels and clinical effects of atorvastatin.
- Beta-adrenergic agonist: Green tea contains caffeine. Concomitant use of large amounts of caffeine might increase cardiac inotropic effects of beta-agonists.
- Cimetidine: Concomitant use might increase the effects and adverse effects of caffeine in green tea.
- Contraceptive medicine: Concomitant use might increase the effects and adverse effects of caffeine found in green tea.
- Disulfiram: Disulfiram might increase the risk of adverse effects from caffeine.
- Ephedrine: Concomitant use might increase the risk for stimulant adverse effects.
- Estrogens: Estrogens might increase the levels and adverse effects of caffeine.
- Fexofenadine: Green tea can decrease blood levels of fexofenadine.
- Fluvoxamine: Fluvoxamine might increase the levels and adverse effects of caffeine.
- Lisinopril: Green tea might reduce the levels and clinical effects of lisinopril.
- Nicotine: Concomitant use might increase the risk of hypertension.
- Nintedanib: Green tea seems to reduce the levels of nintedanib.
- Phenylpropanolamine: Might increase the risk of hypertension, as well as the levels and adverse effects of caffeine.
- Quinolone antibiotics: Might increase the levels and adverse effects of caffeine.
- Stimulant medicine: Concomitant use might increase stimulant adverse effects.
- Theophylline: Green tea might increase the levels and adverse effects of theophylline.

4.6. Fertility, pregnancy and lactation
Safety in fertility, pregnancy and lactation has not been established. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare practitioner for advice before using UriDyn®.

4.7 Effects on ability to drive and use machines
Patients should exercise caution before driving or operating machinery until they are reasonably certain UriDyn® does not adversely affect their performance.

4.8 Undesirable effects
Nervous system disorders:
Frequent: Headache and tingling of extremities.
Gastrointestinal disorders:
Frequent: Bloating, diarrhoea, nausea, vomiting, gastrointestinal discomfort, heartburn, esophagitis, constipation, flatulence.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8

4.9. Overdose
In an overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).
In the event of an overdosage, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES
Category and class:
D 33.7 Combination Product

5.1. Pharmacodynamic properties
D-mannose:
D-mannose interferes with the adhesion of Escherichia coli (E.coli) bacteria to the urinary tract, providing protection from urinary tract infections. By binding to bacteria in urine, the bacteria remain free in the urine and are eliminated upon urination.

Cranberry:
Cranberry extracts enriched in polyphenols including type A PACs, anthocyanins, and flavanols were shown to prevent biofilm formation of pathogenic bacteria. PAC's seem to wrap around E.coli and interferes with bacterial adherence to the urinary tract epithelial cells lining the bladder wall.

Vitamin C:
Vitamin C has a bacteriostatic effect by making the urine more acidic. Large amounts of nitric oxide are released into urine containing nitrites (after moderate acidification) and this release is highly potentialized by the presence of ascorbic acid. This leads to the death of nitrate-reducing bacteria.

2- fucosyllactose:
2-fucosyllactose prevents the adhesion and colonization of E. Coli. 2-fucosyllactose (HMO) acts as a "decoy" receptor for pathogens such as E.coli. Pathogens uses HMO as receptors, preventing them to bind to the glycans of the epithelial cells. The pathogens bound to HMO's are removed with the stools.

Quercetin:
Quercetin has antibacterial properties and inhibits biofilm development of pathogens which prevents bacterial adhesion.

Green tea:
Green tea contains polyphenols, such as catechin epigallocatechin (EGC), that have antimicrobial properties and can fight against the bacteria that cause UTI's. Green tea also has antioxidants that can help with antibiotic-resistant bacteria.

5.2. Pharmacokinetic properties
D-mannose:
Supplemental d-mannose is rapidly absorbed in the gastro-intestinal tract and is excreted in the urine.

Cranberry:
Maximum levels of PAC in plasma occurred between one to three hours after ingestion and is excreted in the urine.

Vitamin C:
Vitamin C is well absorbed in lower doses and is excreted in the urine.

2- fucosyllactose:
No available data.

Quercetin:
The half-life of quercetin and its metabolites range from 6-28 hours and is excreted in the urine as glucuronide and sulphate derivatives, as well as methylated metabolites.

Green tea:
Green tea extract has been shown to rapidly increase general levels of epigallocatechin gallate (EGCG). The half-life of EGCG is approximately 5 hours and is excreted in urine.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Bamboo extract (Bambusa vulgaris Schrad.)
Chicory Fiber (Cichorium intybus L.)
Stearic acid

6.2 Incompatibilities
Not applicable.

6.3. Shelf life
24 months.

6.4 Special precautions for storage
Keep the container tightly closed in a cool, dry place.

6.5 Nature and contents of container
A white 175 ml HDPE bottle with a cap, induction seal, tamper shrink seal and silica gel.
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
Eastgate Extension
Sandton
2146

8. REGISTRATION NUMBER
Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION
Will be allocated by SAHPRA upon registration.