

## PROFESSIONAL INFORMATION

### D 33.7 Combination Product. Complementary Medicine: Health Supplement.

Health supplements are intended only to complement health or supplement the diet. This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

**SCHEDULING STATUS:** [S0]

#### 1. NAME OF THE MEDICINE

BIOGEN WATER DEplete (Vegetable capsules).

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each BIOGEN WATER DEplete vegetable capsules contains: %NRV\*

<i>Arctostaphylos uva-ursi</i> (L) Spreng., folium (Bearberry leaf powder) [Leaf, as 300,00 mg of a 4:1 extract]	1 200,00 mg		
<i>Taraxacum officinale</i> L. (Dandelion) [Root, as 125,00 mg of a 4:1 extract]	500,00 mg		
Potassium (as Tripotassium citrate monohydrate)	33,33 mg		
Magnesium (as Magnesium carbonate)	33,33 mg	8 %	
Pyridoxine (Vitamin B <sub>6</sub> ) (as Pyridoxine hydrochloride)	14,66 mg	862 %	

\*%Nutrient Reference Values (NRVs) for individuals 4 years and older (2010).  
 Sugar free.  
 For a full list of excipients, see section 6.1.

#### 3. PHARMACEUTICAL FORM

Vegetable capsules.

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

BIOGEN WATER DEplete, indicated as a mild diuretic that may assist in the temporarily relief of mild fluid retention while supporting healthy kidney function. May assist with abdominal bloating associated with mild fluid retention and maintain adequate electrolyte balance.

##### 4.2 Posology and method of administration

###### Adults (18 years and older):

Take 1 (one) vegetable capsule 3 (three) times daily before meals, or as recommended by your healthcare provider. If the symptoms persist longer than 2 weeks, it is advised that a healthcare provider is consulted.

###### Paediatric/Adolescent population

BIOGEN WATER DEplete is not recommended for use in children or adolescents below 18 years of age.

##### 4.3 Contraindications

- Patients with a hypersensitivity to any of the ingredients listed under section 6.1.
- Patients with hypersensitivity to birch pollen.
- Patients who suffer from a kidney disorder.
- Patients with a condition where a reduced fluid intake is recommended (e.g. severe cardiac or renal disease).

##### 4.4 Special warnings and precautions for use

Special care should be taken with BIOGEN WATER DEplete. If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine.

Please take note of the following:

- Consult a relevant healthcare provider prior to use if you are pregnant or breastfeeding.
- Consult a relevant healthcare provider prior to use if your goal is to achieve weight loss.
- Consult a health care provider prior to use if you have liver or gall bladder diseases, and / or intestinal obstruction.
- Consult a healthcare provider if symptoms persist or worsen.
- Use in patients with renal failure and / or diabetes, and / or heart failure should be avoided due to the risk of possible hyperkalaemia.
- Consult a healthcare provider if symptoms such as fever, dysuria, spasms or blood in urine occur during the use of BIOGEN WATER DEplete.
- *Uva ursi* (Bearberry leaf) may cause a greenish-brown colouration of the urine.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

##### 4.5 Interaction with other medicines and other forms of interaction

###### Interactions with Medicines

- **Anticoagulant / Antiplatelet medication:**  
Dandelion root along with anticoagulant or antiplatelet drugs might increase the risk of bruising and bleeding.
- **Antidiabetic medication:**  
Dandelion might increase the risk for hypoglycemia when used with antidiabetes drugs.
- **Diuretic medicines:**  
Diuretic medicines may have an additive diuretic effect and can affect electrolyte levels. Concomitant use with potassium-depleting diuretics may increase the risk of hypokalaemia. Caution is advised.
- **Glucuronidated medicine:**  
Bearberry may increase levels of medicines metabolized by glucuronidation.
- **Lithium:**  
The concomitant use of Dandelion and Bearberry leaf with lithium may affect serum lithium levels. Caution is advised.
- **Hepatotoxic medicines:**  
Concomitant use of dandelion with other hepatotoxic medicines such as carbamazepine, isoniazid, methotrexate, paracetamol or herbal supplements with hepatotoxic effects may increase the risk of developing liver damage.
- **Urinary acidifying agents:**  
Effects of bearberry in the urinary tract may be reduced by urinary acidifying agents.

###### Interactions with Diseases/Impairments

- **Bleeding disorders:**  
Dandelion might prolong bleeding time and increase the risk of bruising and bleeding in people with bleeding disorders.
- **Cross-allergenicity:**  
There is concern that dandelion may cause an allergic reaction in individuals sensitive to the Asteraceae / Compositae family.
- **Perioperative:**  
Dandelion might cause excessive bleeding if used perioperatively. Patients are advised to discontinue BIOGEN WATER DEplete at least 2 weeks before elective surgical procedures.
- **Kidney disease:**  
Patients are advised to use potassium supplements with caution in individuals with kidney disease, including chronic kidney disease (CKD), kidney failure or post-kidney transplant, potassium excretion may be affected and increases the risk for elevated potassium levels.

###### Interactions with Food

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting BIOGEN WATER DEplete.

##### 4.6 Fertility, pregnancy and lactation

Safety in fertility, pregnancy and lactation has not been established (see section 4.3).

##### 4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that BIOGEN WATER DEplete does not adversely affect their performance.

##### 4.8 Undesirable effects

###### 4.8 a Summary of safety profile

BIOGEN WATER DEplete can have side effects. Should your general health worsen or if you experience any untoward effects while BIOGEN WATER DEplete, please consult your doctor, pharmacist or other healthcare practitioner for advice.

###### 4.8 b Summary of adverse reactions

BIOGEN WATER DEplete can have side effects. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist. Hypersensitivity: *Unknown frequency*: Allergic reactions. Gastrointestinal complaints: *Unknown frequency*: Nausea, vomiting, stomach-ache have been reported. Epigastric pain and hyperacidity.

##### 4.9 Overdose

Should your general health worsen or if you experience any untoward effects while BIOGEN WATER DEplete, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking BIOGEN WATER DEplete and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BIOGEN WATER DEplete. You may need urgent medical attention or hospitalisation. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity. Treatment of overdose is symptomatic and supportive.

##### 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: <https://www.sahpra.org.za/Publications/Index/8>.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

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#### Mechanism of action:

**Dandelion:** Evidence from animal research suggests that dandelion has diuretic activity. It appears the sesquiterpene lactones found in dandelion are responsible for its diuretic effects.

**Bearberry Leaf:** May have urinary disinfectant properties which may be beneficial for protection from urolithiasis, possibly due to the presence of saponins. Some research shows that uva ursi can increase urine flow, suggesting diuretic effects.

**Birch Leaf:** The diuretic effects of birch leaf are due to the flavonoid constituents. These constituents increase urine volume (water loss) but not electrolyte excretion.

**Potassium:** Necessary for maintaining both water and electrolyte balance.

**Magnesium:** Magnesium inhibits the maturation of calciprotein particles. Calcium and phosphate concentrations in the circulation are supersaturated. They aggregate to form calcium-phosphate clusters. These clusters induce calcification of vascular smooth muscle cells as well as inflammation/oxidative stress and may also be involved in kidney injury.

**Pyridoxine (Vitamin B<sub>6</sub>):** For kidney stones, Vitamin B<sub>6</sub> is thought to be beneficial by decreasing urinary excretion of oxalate in some patients. Most kidney stones are composed of calcium oxalate, and high urinary oxalate has been associated with development and recurrence of kidney stones.

### 5.2 Pharmacokinetic properties

#### Dandelion:

There is insufficient reliable information available about the pharmacokinetics.

#### Bearberry Leaf:

Absorption: Arbutin, a constituent of uva ursi and precursor of hydroquinone, is rapidly absorbed via the sodium-glucose carrier in the small intestine after oral administration.

Distribution: The amount of free hydroquinone detected in tissues, organs, and bones, is less than 2% of the total arbutin dose administered.

Metabolism: Arbutin, a constituent of uva ursi, is first broken down in the liver to hydroquinone and glucose. Hydroquinone is immediately metabolized by conjugation with glucuronic acid or sulfate; these metabolites are not toxic. A small amount of unconjugated ("free") hydroquinone remains; this should be the only portion considered for safety concerns.

Excretion: Hydroquinone is excreted in the urine, with about 85% in the conjugated form and 0.6% unconjugated.

#### Birch Leaf:

There is insufficient reliable information available about the pharmacokinetics.

#### Potassium:

There is insufficient reliable information available about the Absorption, Metabolism and Excretion of Potassium.

Distribution: Total body potassium is regulated by the kidney.

#### Magnesium:

Absorption: Magnesium requires both parathyroid hormone and vitamin D for absorption. It is absorbed throughout the gastrointestinal tract and about one third of dietary magnesium is absorbed.

Distribution: The body contains about 25 grams of magnesium, which is divided in roughly equal portions between the skeleton and soft tissue. Factors which play a role in magnesium reabsorption include parathyroid hormone, plasma magnesium and calcium level alterations, and use of loop diuretics.

Excretion: Magnesium excretion is primarily via the kidneys and averages only 3% to 5% of the filtered load.

#### Pyridoxine (Vitamin B<sub>6</sub>):

Absorption: Vitamin B<sub>6</sub> is absorbed passively in the upper gastrointestinal tract.

Metabolism: In the liver, vitamin B<sub>6</sub> is converted to the coenzyme pyridoxal phosphate.

Excretion: Vitamin B<sub>6</sub> metabolites are excreted in the urine.

### 5.3 Preclinical safety data (Adults)

When used orally and appropriately in adults, the ingredients in BIOGEN WATER DEplete is recognized as possibly safe.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Vegetable capsules (Hypromellose, Carrageenan, Titanium Dioxide, Purified Water), Magnesium Stearate, Maltodextrin.

### 6.2 Incompatibilities

No compatibility studies have been performed; BIOGEN WATER DEplete must not be mixed with other medications.

### 6.3 Shelf Life

24 Months.

### 6.4 Special precautions for storage

- Protect from moisture and store at or below 25 °C.
- KEEP OUT OF REACH OF CHILDREN.
- Do not use after the expiry date stated on the label.
- Return all unused BIOGEN WATER DEplete to your pharmacist.
- Do not dispose of unused BIOGEN WATER DEplete in drains or sewerage systems (e.g. toilets).

### 6.5 Nature and contents

90 White to off-white vegetable capsules are available in a white 250 ml PET container sealed with a white plastic screw cap. The container contains a non-edible silica gel sachet and a foam insert.

### 6.6 Special precautions for disposal

No special requirements.

## 7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen.  
 23 Stag Road,  
 Glen Austin,  
 South Africa.  
 Tel: 0860 347 243.  
 Email: info@biogen.co.za  
 Website: www.biogen.co.za

## 8. REGISTRATION NUMBER


Will be allocated by SAHPRA upon registration.

## 9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

## 10. DATE OF REVISION OF THE TEXT

August 2023.

<b>JOB:</b> BPS_BIOGEN WATER DEplete (90's)	<b>SIZE:</b> 245mm x 285mm
<b>STOCK:</b> Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input type="checkbox"/> Other: <input checked="" type="checkbox"/>	
<b>COLOURS:</b>  K	<b>FINISHING:</b> <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
<b>PLEASE CHECK CAREFULLY</b> Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.	