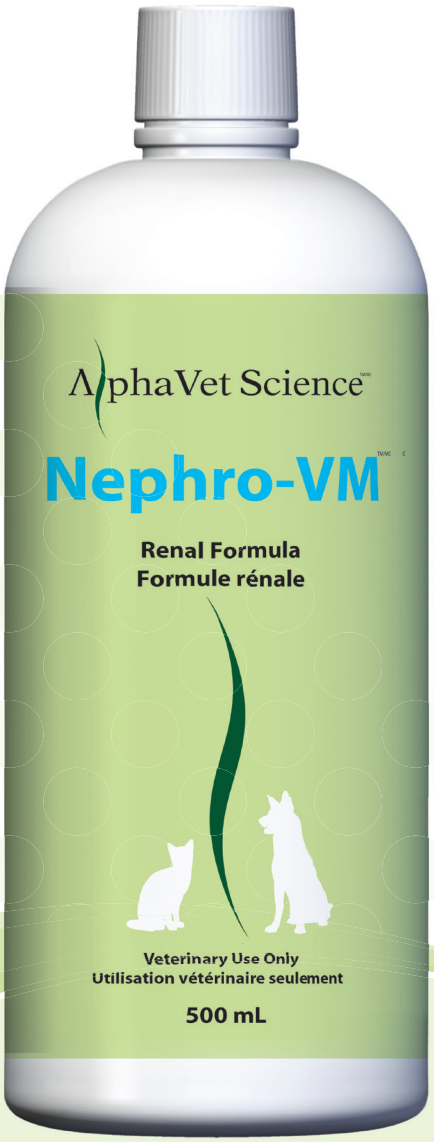
AlphaVet Science™/MC



Just Natural Science™

La science au naturel, simplement™

AlphaVet Science™

Nephro-VM™

Nephro-VM™ reduces oxidative stress and supports optimal bladder function and health of the kidneys.

INDICATIONS
- Urinary tract infections
- Urolithiasis

INGREDIENTS ACTIONS
- Alterative
- Anti-inflammatory
- Antilithic
- Anti-oedemic
- Anti-oxidant
- Astringent
- Anti-uricemic
- Bladder tonic
- Diuretic
- Genitourinary antiseptic
- Lenitive
- Lithotriptic
- Renal tonic
- Nephroprotective

ADMINISTRATION Oral

DOSAGE

1 - 10 lbs	2.5 mL (½ teaspoon) daily.
11 - 20 lbs	5 mL (1 teaspoon) daily.
21 - 50 lbs	7.5 mL (1½ teaspoons) daily.
51 - 100 lbs	10 mL (2 teaspoons) daily.
> 100 lbs	15 mL (1 tablespoon) daily.

STORAGE Refrigerate after opening. Keep bottle cap tightly closed when not in use.

PACKAGING 500 mL/bottle

Nephro-VM™ FORMULA

1 teaspoon (5 mL) contains:

Chanca Piedra Herb	(*Phyllanthus niruri*/Herba Phyllanthi)	100 mg
Chinese Magnoliavine Fruit	(*Schisandra chinensis*/Fructus Schisandrae)	100 mg
Christina Loosestrife Herb	(*Lysimachia christinae*/Herba Lysimachiae)	100 mg
Three-Leaved Caper Bark	(*Crataeva nurvala*/Cortex Crataeva Nurvala)	100 mg
Bearberry Leaf	(*Arctostaphylos uva-ursi*/Folium Uvae Ursi)	75 mg
Puncture Vine Fruit	(*Tribulus terrestris*/Fructus Tribuli)	75 mg
Stinging Nettle Root	(*Urtica dioica*/Radix Urticae Dioicae)	75 mg
Corn Silk	(*Zea mays*/Stigmata Maydis Zeae)	50 mg
Field Horsetail Herb	(*Equisetum arvense*/Herba Equiseti Arvensis)	50 mg

NON-MEDICINAL INGREDIENTS

Stevia, Citric acid, Potassium sorbate, Purified water, Sodium benzoate.

Nephro-VM™ is manufactured under strict GMP standards and contains no dairy, yeast, wheat or gluten. Does not contain animal by-products.

PHARMACOLOGICAL ACTIVITIES - TOXICOLOGY - DRUG INTERACTIONS

Phyllanthus niruri (Chanca Piedra)

In traditional medicine Herba Phyllanthi is used in the treatment of urolithiasis and cholelithiasis, hence the name 'stone breaker' (Williamson, 2002). Herba Phyllanthi has undergone mechanistic *in vitro*, animal, and clinical trials that support its impact on calcium oxalate crystallization (Kieley *et al.*, 2008). In a randomized, prospective, long-term human study, regular administration of Herba Phyllanthi after extracorporeal shock wave lithotripsy for renal stones, resulted in an increased stone-free rate in patients with renal stones (Micali *et al.*, 2006). Herba Phyllanthi has shown an inhibitory effect on calcium oxalate crystal growth and aggregation in human urine *in vitro* suggesting that it may interfere with the early stages of stone formation and can be beneficial in the treatment and/or prevention of urolithiasis (Barros *et al.*, 2003).

TOXICOLOGY

Toxicity for Herba Phyllanthi has not been documented in dogs and cats when administered orally in therapeutic doses. The extract of Herba Phyllanthi is non-toxic having oral LD_{50} > 5 g/kg of body weight in mice (Evi *et al.*, 2008).

Equivalent toxic dose in 20 kg dog: >100 g PO of Herba Phyllanthi extract.
Equivalent toxic dose in 5 kg cat: >25 g PO of Herba Phyllanthi extract.

DRUG INTERACTIONS

Validated interactions studies do not exist for Herba Phyllanthi preparations. Clinical interactions with other drugs have not been reported. However, Herba Phyllanthi preparations may potentiate insulin and anti-diabetic drugs due to its hypoglycemic effect (Brinker, 1998).

Schisandra chinensis (Chinese Magnoliavine)

Fructus Schisandrae has been described in pharmacopoeias and well established studies as a general tonic for treating fatigue associated with illness and in treating urinary tract disorders (WHO, 2007). Schisandrol B, an active constituent of Fructus Schisandrae, enhances renal mitochondrial antioxidant status and the level/activity of reduced glutathione, α-tocopherol and Manganese superoxide dismutase (Chiu *et al.*, 2008). Schisandrol B and Schisandrol C have been found to exert anti-inflammatory effects in experimental studies (WHO, 2007).

TOXICOLOGY

Schisandra chinensis

Toxicity for Fructus Schisandrae has not been documented in dogs and cats when administered orally in therapeutic doses. Acute toxicity test showed that ethanol extract of Fructus Schisandrae was relatively non-toxic, with an oral LD_{50} value of 35.63 ± 6.46 g/kg of body weight in mice (Pan *et al.*, 2011).

Equivalent toxic dose in 20 kg dog: 715 g PO of Fructus Schisandrae ethanol extract.
Equivalent toxic dose in 5 kg cat: 180 g PO of Fructus Schisandrae ethanol extract.

DRUG INTERACTIONS

Validated interactions studies do not exist for Fructus Schisandrae preparations. Clinical interactions with other drugs have not been reported. However, in an animal study, Fructus Schisandrae extract has been shown to inhibit CYP3A (Lai *et al.*, 2009) and may affect the intracellular concentration of drugs metabolized by this enzyme.

Lysimachia christinae (Christina Loosestrife)

In experimental studies, the aqueous extract of Herba Lysimachiae has demonstrated potent hypouricemic effects (Wang *et al.*, 2002). In animal models, orally administered Herba Lysimachiae extract rendered the urine acidic, promoting the dissolution of stones formed under alkaline conditions (Zhu, 1998). Quercetin, quercetin 3-O-β-D-glucopyranoside, and kaempferol 3-O-β-D-glucopyranoside are the major constituents of Herba Lysimachiae that have exhibited free radical scavenging activity (Huang *et al.*, 2006). Flavonoids and phenolic acids of Herba Lysimachiae have anti-inflammatory activity (Gu *et al.*, 1988).

TOXICOLOGY

Toxicity for Herba Lysimachiae has not been documented in dogs and cats when administered orally in therapeutic doses. The LD_{50} value for Herba Lysimachiae has not been determined.

DRUG INTERACTIONS

Validated interactions studies do not exist for Herba Lysimachiae preparations. Clinical interactions with other drugs have not been reported.

Crataeva nurvala (Three-Leaved Caper)

In traditional medicine, Cortex Crataeva Nurvala is highly acclaimed for its use in the management of urinary tract disorders, especially urolithiasis and in ethnoveterinary medicine Cortex Crataeva Nurvala has been used in the treatment of renal lithiasis (Williamson, 2002). Pentacyclic triterpenes lupeol and lupeol linoleate isolated from Cortex Crataeva Nurvala, have been shown to minimize the deposition of stone-forming components in kidneys (Remya *et al.*, 2009) such as calcium, oxalate, urate, cystine, xanthine, and phosphate. Cortex Crataeva Nurvala decoction reduces the urinary excretion of sodium and magnesium, shifting values from the lithogenic to the nonlithogenic zone (Deshpande *et al.*, 1982). In animal models Cortex Crataeva Nurvala extracts have been shown to exert a regulatory action on endogenous oxalate synthesis by reducing oxalate-synthesizing liver enzyme, glycolate oxidase (Varalakshmi *et al.*, 1990; Patankar *et al.*, 2008).

TOXICOLOGY

Toxicity for Cortex Crataeva Nurvala has not been documented in dogs and cats when administered orally in therapeutic doses. Intraperitoneal LD_{50} of Cortex Crataeva Nurvala extract is >1,000 mg/kg of body weight in adult rats (Williamson, 2002).

Equivalent toxic dose in 20 kg dog: >20,000 mg IP of Cortex Crataeva Nurvala extract.
Equivalent toxic dose in 5 kg cat: >5,000 mg IP of Cortex Crataeva Nurvala extract.

DRUG INTERACTIONS

Validated interactions studies do not exist for Cortex Crataeva Nurvala preparations. Clinical interactions with other drugs have not been reported.

Arctostaphylos uva-ursi (Bearberry)

Folium Uvae Ursi is listed in The German Pharmacopoeia as a urinary disinfectant for the treatment of bladder and kidney catarrh and inflammation. The European Scientific Cooperative on Phytotherapy (ESCOP) lists Folium Uvae Ursi as a treatment for uncomplicated cystitis where antibiotics are not warranted. The German Commission E Monographs recommends it for inflammatory conditions of the lower urinary tract. Folium Uvae Ursi has been reported to be a diuretic, bacteriostatic, and astringent and has been used in the treatment of urinary tract disorders (Martindale, 1996).

TOXICOLOGY

Arctostaphylos uva-ursi

Toxicity for Folium Uvae Ursi has not been documented in dogs and cats when administered orally in therapeutic doses. No data on single or repeated dose toxicity has been reported for Folium Uvae Ursi extract (EMEA, 2011).

DRUG INTERACTIONS Validated interactions studies do not exist for Folium Uvae Ursi preparations. Clinical interactions with other drugs have not been reported.

Tribulus terrestris (Puncture Vine)

In traditional medicine, Fructus Tribuli is used in the treatment of urolithiasis. It is also used as a diuretic (WHO, 2009). Extract of Fructus Tribuli has exhibited a concentration dependent inhibition of nucleation and the growth of calcium oxalate crystals (Aggarwal *et al.*, 2010). Ethanol extract of Fructus Tribuli showed significant dose dependent protection against uroliths induced by glass bead implantation in albino rats. The extract provided significant protection against deposition of calculogenic material around the glass bead. It also protected against leukocytosis and elevation of serum urea levels (Anand *et al.*, 1994). In a study, aqueous extract of Fructus Tribuli elicited a positive diuresis, which was slightly more than that of furosemide. The diuretic and contractile effects of Fructus Tribuli indicate that it has the potential of propelling urinary stones (Al-Ali *et al.*, 2003). A dried extract of Fructus Tribuli induced diuresis and increased creatinine clearance in anaesthetized dogs (Van Valkenburg & Bunyapraphatsara, 2003). Oral administration of Fructus Tribuli extract provided protection against the mercuric chloride induced toxicity in mice kidney tissue (Kavitha & Jagadeesan, 2006) and reduced hyperoxaluria-caused oxidative stress, and restored antioxidant enzyme activity and their expression profile in kidney tissue (Kamboj *et al.*, 2011).

TOXICOLOGY

Toxicity for Fructus Tribuli has not been documented in dogs and cats when administered orally in therapeutic doses. Intraperitoneal LD_{50} of lyophilized saponin mixture of Fructus Tribuli is 813 mg/kg of body weight in mice (Arcasoy *et al.*, 1998).

Equivalent toxic dose in 20 kg dog: 16,260 mg IP of lyophilized saponin mixture of Fructus Tribuli.
Equivalent toxic dose in 5 kg cat: 4,065 mg IP of lyophilized saponin mixture of Fructus Tribuli.

DRUG INTERACTIONS Validated interactions studies do not exist for Fructus Tribuli preparations. Clinical interactions with other drugs have not been reported.

Urtica dioica (Stinging Nettle)

Nicolaus Copernicus (1473-1523), renowned astronomer, used Herba Urticae Dioicae as a remedy for symptoms of renal colic and hematuria (Popowska-Drojecka *et al.*, 2011). In recent years, many therapeutic effects such as diuretic, natriuretic, hypotensive, anti-rheumatic, anti-prostatic, and *in vitro* anti-oxidant effects of Herba Urticae Dioicae have been determined (Cetinus *et al.*, 2005). Clinical data supports the use of Radix Urticae Dioicae in the symptomatic treatment of lower urinary tract disorders such as nocturia, polyuria, and urinary retention (WHO, 2004).

TOXICOLOGY

Toxicity for Radix Urticae Dioicae has not been documented in dogs and cats when administered orally in therapeutic doses. However, there is a reported incidence of hunting dogs in the United States that were poisoned and died after massive exposure to the stings of the Urtica species of nettle (Bassett *et al.*, 1977). Other reports have indicated that the effects experienced by hunting dogs appear to represent a condition other than contact urticaria and may be due to another plant commonly labelled as nettle, possibly *Urtica chamaedryoides*, indicated in some literature as the "guilty" plant (Edom, 2002). In rats the oral LD_{50} of Radix Urticae Dioicae was suggested to be >30g/kg of body weight and intraperitoneal LD_{50} to be >3 g/kg of body weight (EMEA, 2011).

Equivalent toxic dose in 20 kg dog: >600 g PO of Radix Urticae Dioicae.
Equivalent toxic dose in 5 kg cat: >150 g PO of Radix Urticae Dioicae.

DRUG INTERACTIONS

Validated interactions studies do not exist for Radix Urticae Dioicae preparations. Clinical interactions with other drugs have not been reported. However, Folium Urticae Dioicae extract significantly lowers cytochrome P450 enzymes (Ozen & Korkmaz, 2003) and can affect the intracellular concentration of drugs metabolized by this enzyme.

Zea mays (Corn Silk)

Stigmata Maydis Zeae is the silky tassel inside the corn husk, not often considered a food, but it is highly regarded in herbology as a valuable support for the urinary system. Stigmata Maydis Zeae is an effective diuretic and it has been used to treat acute and chronic bladder infection, cystitis, urethritis, and urolithiasis. Stigmata Maydis Zeae also helps to ease oedema and swelling caused by many inflammatory conditions. In animal models, extracts of Stigmata Maydis Zeae modify glomerular function and potassium urinary excretion (Velazquez *et al.*, 2005).

TOXICOLOGY

Zea mays

Toxicity for Stigmata Maydis Zeae has not been documented in dogs and cats when administered orally in therapeutic doses. Intraperitoneal LD_{50} of Stigmata Maydis Zeae methanol extract is 3,464.10 mg/kg of body weight in mice (Ajali *et al.*, 2007).

Equivalent toxic dose in 20 kg dog: 69,282 mg IP of Stigmata Maydis Zeae methanol extract.
Equivalent toxic dose in 5 kg cat: 17,320 mg IP of Stigmata Maydis Zeae methanol extract.

DRUG INTERACTIONS

Validated interactions studies do not exist for Stigmata Maydis Zeae preparations. Clinical interactions with other drugs have not been reported. However, in animal studies, Stigmata Maydis Zeae extract has been shown to exert hypoglycaemic effect (Guo *et al.*, 2009) and may potentiate insulin and anti-diabetic drugs.

Equisetum arvense (Field Horsetail)

Evidence suggests that Herba Equiseti Arvensis has mild diuretic action which is likely due to the constituents, equisetonin and flavone glycosides. In a study of a herbal extract compound consisting of Herba Equiseti Arvensis and Stigmata Maydis Zeae, the diuretic effect was found to be greater than hydrochlorothiazide suspension (Masteiková *et al.*, 2007).

TOXICOLOGY

Toxicity for Herba Equiseti Arvensis has not been documented in dogs and cats when administered orally in therapeutic doses. However, Herba Equiseti Arvensis is toxic to horses, especially younger animals. Poisoning may occur on pasture, but mostly in winter when contaminated hay is fed. Toxicity is rare in cattle and sheep (Beasley, 1999). The toxic principle is thiaminase, an enzyme that cleaves the thiamine molecule and renders it biologically inactive. Thiaminases are denatured by heat, therefore subjecting any of the sources of thiaminases to cooking or other heat treatment will render the thiaminases inactive (Cornell, 2009). Intraperitoneal LD_{50} of Herba Equiseti Arvensis extract is >1,000 mg/kg of body weight in mice (EMEA, 2008). Oral LD_{50} of Herba Equiseti Arvensis is >1.79 g/kg of body weight and >1.85 g/kg of body weight in female and male rats respectively (Tago *et al.*, 2010).

Equivalent toxic dose in 20 kg dog: > 36 g PO of Herba Equiseti Arvensis.
Equivalent toxic dose in 5 kg cat: > 9 g PO of Herba Equiseti Arvensis.

DRUG INTERACTIONS

Validated interactions studies do not exist for Herba Equiseti Arvensis preparations. Clinical interactions with other drugs have not been reported. An *in vitro* study indicates that Herba Equiseti Arvensis has a low effect on CYP3A4 and CYP19 activity. A clinical interaction study was conducted with a combination of Cortex Crataeva Nurvala extract and Herba Equiseti Arvensis in undefined composition and dosage. There was a lack of interference with CYP450 (EMEA, 2008).

SAFETY INFORMATION

PRECAUTIONS

- An examination from a veterinarian is recommended prior to using this product.
- Safe use in pregnant animals or animals intended for breeding has not been proven.
- If animal's condition worsens or does not improve, stop product administration and consult your veterinarian.
- Not to be used one week prior to surgery.
- Consult your veterinarian for potential drug interactions.
- Off-label use of this product in ruminants is not recommended.
- Administer during or after the animal has eaten to reduce incidence of gastrointestinal upset.
- Oral use only.
- Shake well before use.

WARNINGS

- To be used in dogs and cats only.
- Keep out of reach of children and animals.
- In case of accidental overdose, contact a health professional immediately.

ADVERSE REACTIONS

The presence of hydroquinone in *Arctostaphylos uva-ursi* may impart a greenish-brown colour to the urine, which darkens following exposure to air due to oxidation of hydroquinone [dose related] (Newall *et al.*, 1996).

CONTRAINDICATIONS

- Contraindicated in pregnant and nursing dogs and cats.
- Contraindicated in dehydrated patients.

AlphaVet Science™

Nephro-VM™

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