OXALTEM- berberis vulgaris, oxalicum acidum, sanguinaria canadensis, chimaphila umbellata, calcarea fluorica, calcarea silicata, uricum acidum, calcarea phosphorica, parathormonum, pyridoxinum hydrochloricum liquid Nucleic Products, LLC

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

DRUG FACTS:

ACTIVE INGREDIENTS:

Berberis Vulgaris 6X, 9X, 12X, Oxalicum Acidum 6X, 9X, 12X, 30C, Sanguinaria Canadensis 9X, Chimaphila Umbellata 9X, 30C, Calcarea Fluorica 12X 30C, Calcarea Silicata 12X 30C, Uricum Acidum 12X, 30C, Calcarea Phosphorica 6C, 9C, 30C, Parathormonum 9C, Pyridoxinum Hydrochloricum 12C.

PURPOSE:

Homeopathic medicine for the regulation of oxalate deposition and related dysfunctions of drainage.

Claims based on homeopathic theory, not accepted medical evidence. Not FDA evaluated.

WARNINGS:

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Do not use if seal is broken or missing.

This Product does not contain sugar, starch, salt, preservatives, artificial flavors or additives, and no wheat, gluten, soy or milk derivatives.

KEEP OUT OF REACH OF CHILDREN:

In case of overdose, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

Place drops under tongue 30 minutes before/after meals. Adults and children 12 years and over: Take one full dropper up to 2 times a day. Consult a physician for use in children under 12 years of age.

INDICATIONS:

Homeopathic medicine for the regulation of oxalate deposition and related dysfunctions of drainage.

Claims based on homeopathic theory, not accepted medical evidence. Not FDA evaluated.

INACTIVE INGREDIENTS

20% organic ethanol, purified water

QUESTIONS:

Distributed By: Nucleic Products, LLC

PO Box 7148 Grove, OK 74344

PACKAGE LABEL DISPLAY:

NDC: 75053-0012-1

Nu cleic

Oxaltem

Homeopathic Medicine

For Professional Use Only

4 fl oz. (118 ml)



OXALTEM

berberis vulgaris, oxalicum acidum, sanguinaria canadensis, chimaphila umbellata, calcarea fluorica,

calcarea silicata, uricum acidum, calcarea phosphorica, parathormonum, pyridoxinum hydrochloricum liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75053-0012
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BERBERIS VULGARIS ROOT BARK (UNII: 1TH8Q20J0U) (BERBERIS VULGARIS ROOT BARK - UNII:1TH8Q20J0U)	BERBERIS VULGARIS ROOT BARK	6 [hp_X] in 1 mL	
OXALIC ACID DIHYDRATE (UNII: 0K2L2IJ590) (OXALIC ACID - UNII:9E7R5L6H31)	OXALIC ACID DIHYDRATE	6 [hp_X] in 1 mL	
SANGUINARIA CANADENSIS ROOT (UNII: N9288CD508) (SANGUINARIA CANADENSIS ROOT - UNII:N9288CD508)	SANGUINARIA CANADENSIS ROOT	9 [hp_X] in 1 mL	
CHIMAPHILA UMBELLATA WHOLE (UNII: WCK21A9W9J) (CHIMAPHILA UMBELLATA - UNII: WCK21A9W9J)	CHIMAPHILA UMBELLATA WHOLE	9 [hp_X] in 1 mL	
CALCIUM FLUORIDE (UNII: O3B55K4YKI) (FLUORIDE ION - UNII:Q80VPU4080)	CALCIUM FLUORIDE	12 [hp_X] in 1 mL	
CALCIUM SILICATE (UNII: S4255P4G5M) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM SILICATE	12 [hp_X] in 1 mL	
URIC ACID (UNII: 268B43MJ25) (URIC ACID - UNII:268B43MJ25)	URIC ACID	12 [hp_X] in 1 mL	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	6 [hp_C] in 1 mL	
PARATHYROID HORMONE (UNII: N19A0T0E5J) (PARATHYROID HORMONE - UNII:N19A0T0E5J)	PARATHYROID HORMONE	9 [hp_C] in 1 mL	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII: KV2JZ 1BI6Z)	PYRIDOXINE	12 [hp_C] in 1 mL	

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
ALCOHOL (UNII: 3K9958V90M)				

l	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
		NDC:75053- 0012-1	118 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/21/2024		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		05/21/2024	
homeopathic		03/21/2024	

Labeler - Nucleic Products, LLC (117470417)

Registrant - Apotheca Company (844330915)

Establishment			
Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	$manufacture (75053-0012) \; , \; api \; manufacture (75053-0012) \; , \; label (75053-0012) \; , \\ pack (75053-0012) \; . \\$

Revised: 5/2024 Nucleic Products, LLC