

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,

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.

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: 75053-0009-1

Nu cleic

Oxaltem

Homeopathic Medicine

For Professional Use Only

4 fl oz. (118 ml)

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

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

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.

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

NDC: 75053-0009-1

Nu cleic

Oxaltem
Homeopathic Medicine
20% Organic Ethanol
For Professional Use Only
4 fl oz. (118 ml)

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.

Inactive Ingredients: 20% organic ethanol, purified water

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.

LOT:

Distributed By: Nucleic Products, LLC
PO Box 7148 Grove, OK 74344

OXALTEM

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

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

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:75053-0009 |
| 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 (UNII: 9E7R5L6H31) (OXALIC ACID - UNII:9E7R5L6H31) | OXALIC ACID | 6 [hp_X] in 1 mL |
| SANGUINARIA CANADENSIS WHOLE (UNII: B3XJA0OV6T) (SANGUINARIA CANADENSIS WHOLE - UNII:B3XJA0OV6T) | SANGUINARIA CANADENSIS WHOLE | 9 [hp_X] in 1 mL |
| CHIMAPHILA UMBELLATA WHOLE (UNII: WCK21A9W9J) (CHIMAPHILA UMBELLATA WHOLE - UNII:WCK21A9W9J) | CHIMAPHILA UMBELLATA WHOLE | 9 [hp_X] in 1 mL |
| CALCIUM FLUORIDE (UNII: O3B55K4YKI) (FLUORIDE ION - UNII:Q80VPU408O) | 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:KV2JZ1BI6Z) | PYRIDOXINE | 12 [hp_C] in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------------|----------|
| WATER (UNII: 059QF0KO0R) | |
| ALCOHOL (UNII: 3K9958V90M) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:75053-0009-1 | 118 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | 01/31/2022 | 07/26/2028 |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| unapproved homeopathic | | 01/31/2022 | 07/26/2028 |

Labeler - Nucleic Products, LLC (117470417)

Registrant - Apotheca Company (844330915)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|--|
| Apotheca Company | | 844330915 | manufacture(75053-0009) , api manufacture(75053-0009) , label(75053-0009) , pack(75053-0009) |

Revised: 5/2024

Nucleic Products, LLC