

POLLEN MIX- american elm, plane (sycamore), ash, beech, willow, elder (box elder), alder, cedar, maple, hazel, poplar, kentucky bluegrass, orchard grass, silver birch, bermuda grass, johnson grass, rye grass, vernal grass, bahia grass, oak, hickory, timothy grass liquid
BioActive Nutritional, Inc.

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:

American Elm 16X, 24X, 30X, Plane (Sycamore) 16X, 24X, 30X, Ash 16X, 24X, 30X, Beech 16X, 24X, 30X, Willow 16X, 24X, 30X, Elder (Box Elder) 16X, 24X, 30X, Alder 16X, 24X, 30X, Cedar 16X, 24X, 30X, Maple 16X, 24X, 30X, Hazel 16X, 24X, 30X, Poplar 16X, 24X, 30X, Kentucky Bluegrass 16X, 24X, 30X, Orchard Grass 16X, 24X, 30X, Silver Birch 16X, 24X, 30X, Bermuda Grass 16X, 24X, 30X, Johnson Grass 16X, 24X, 30X, Rye Grass 16X, 24X, 30X, Vernal Grass 16X, 24X, 30X, Bahia Grass 16X, 24X, 30X, Oak 16X, 24X, 30X, Hickory 16X, 24X, 30X, Timothy Grass 16X, 24X, 30X.

INDICATIONS:

For temporary relief of allergies due to pollen.

WARNINGS:

If pregnant or breast-feeding, ask a health care 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 tamper evident seal is broken or missing.

Store in cool, dry place.

KEEP OUT OF REACH OF CHILDREN:

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

DIRECTIONS:

10 drops orally, 3 times a day. Consult a physician for use in children under 12 years of age.

INDICATIONS:

For temporary relief of allergies due to pollen.

INACTIVE INGREDIENTS:

Demineralized Water, 25% Ethanol

QUESTIONS:

Distributed by:

BioActive Nutritional, Inc.

1803 N. Wickham Rd.

Melbourne, FL 32935

bioactivenutritional.com

PACKAGE LABEL DISPLAY:

BIOActive Nutritional

POLLEN MIX

HOMEOPATHIC

1 FL OZ (30 ml)



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LOT:

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POLLEN MIX HOMEOPATHIC

ACTIVE INGREDIENTS:

Alder 16X, 24X, 30X, American Elm 16X, 24X, 30X, Ash 16X, 24X, 30X, Bahia Grass 16X, 24X, 30X, Beech 16X, 24X, 30X, Bermuda Grass 16X, 24X, 30X, Cedar 16X, 24X, 30X, Elder (Box Elder) 16X, 24X, 30X, Hazel 16X, 24X, 30X, Hickory 16X, 24X, 30X, Johnson Grass 16X, 24X, 30X, Kentucky Bluegrass 16X, 24X, 30X, Maple 16X, 24X, 30X, Oak 16X, 24X, 30X, Orchard Grass 16X, 24X, 30X, Plane (Sycamore) 16X, 24X, 30X, Poplar 16X, 24X, 30X, Rye Grass 16X, 24X, 30X, Silver Birch 16X, 24X, 30X, Timothy Grass 16X, 24X, 30X, Vernal Grass 16X, 24X, 30X, Willow 16X, 24X, 30X.

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43857-0535
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ULMUS AMERICANA POLLEN (UNII: 89BAT511BD) (ULMUS AMERICANA POLLEN - UNII:89BAT511BD)	ULMUS AMERICANA POLLEN	16 [hp_X] in 1 mL
PLATANUS X ACERIFOLIA POLLEN (UNII: 77X11O684J) (PLATANUS X ACERIFOLIA POLLEN - UNII:77X11O684J)	PLATANUS X ACERIFOLIA POLLEN	16 [hp_X] in 1 mL
FRAXINUS EXCELSIOR POLLEN (UNII: 1824QUA0U3) (FRAXINUS EXCELSIOR POLLEN - UNII:1824QUA0U3)	FRAXINUS EXCELSIOR POLLEN	16 [hp_X] in 1 mL
FAGUS SYLVATICA POLLEN (UNII: 63218N1ZBI) (FAGUS SYLVATICA POLLEN - UNII:63218N1ZBI)	FAGUS SYLVATICA POLLEN	16 [hp_X] in 1 mL
SALIX X FRAGILIS POLLEN (UNII: UQ7Z2EA3ZI) (SALIX X FRAGILIS POLLEN - UNII:UQ7Z2EA3ZI)	SALIX X FRAGILIS POLLEN	16 [hp_X] in 1 mL
SAMBUCUS CANADENSIS FLOWER (UNII: C87P971T6W) (SAMBUCUS CANADENSIS FLOWER - UNII:C87P971T6W)	SAMBUCUS CANADENSIS FLOWER	16 [hp_X] in 1 mL
ALNUS RUBRA POLLEN (UNII: Z0F2YK1B7H) (ALNUS RUBRA POLLEN - UNII:Z0F2YK1B7H)	ALNUS RUBRA POLLEN	16 [hp_X] in 1 mL
JUNIPERUS VIRGINIANA POLLEN (UNII: PY0JA16R2G) (JUNIPERUS VIRGINIANA POLLEN - UNII:PY0JA16R2G)	JUNIPERUS VIRGINIANA POLLEN	16 [hp_X] in 1 mL
ACER SACCHARUM POLLEN (UNII: V38QUQ7861) (ACER SACCHARUM POLLEN - UNII:V38QUQ7861)	ACER SACCHARUM POLLEN	16 [hp_X] in 1 mL
CORYLUS AVELLANA POLLEN (UNII: CR2J49TL6L) (CORYLUS AVELLANA POLLEN - UNII:CR2J49TL6L)	CORYLUS AVELLANA POLLEN	16 [hp_X] in 1 mL
POPULUS ALBA POLLEN (UNII: VU8C8SB23P) (POPULUS ALBA POLLEN - UNII:VU8C8SB23P)	POPULUS ALBA POLLEN	16 [hp_X] in 1 mL
POA PRATENSIS POLLEN (UNII: SCB8J7LS3T) (POA PRATENSIS POLLEN - UNII:SCB8J7LS3T)	POA PRATENSIS POLLEN	16 [hp_X] in 1 mL
DACTYLIS GLOMERATA POLLEN (UNII: 83N78IDA7P) (DACTYLIS GLOMERATA POLLEN - UNII:83N78IDA7P)	DACTYLIS GLOMERATA POLLEN	16 [hp_X] in 1 mL
BETULA PENDULA POLLEN (UNII: ZL5TV40C5Y) (BETULA PENDULA POLLEN - UNII:ZL5TV40C5Y)	BETULA PENDULA POLLEN	16 [hp_X] in 1 mL
CYNODON DACTYLON POLLEN (UNII: 175F461W10) (CYNODON DACTYLON WHOLE - UNII:2Q8MR21NHK)	CYNODON DACTYLON POLLEN	16 [hp_X] in 1 mL
SORGHUM HALEPENSE POLLEN (UNII: 577VA5B4HP) (SORGHUM HALEPENSE POLLEN - UNII:577VA5B4HP)	SORGHUM HALEPENSE POLLEN	16 [hp_X] in 1 mL
SECALE CEREALE POLLEN (UNII: I6KAZ8AO1O) (SECALE CEREALE POLLEN - UNII:I6KAZ8AO1O)	SECALE CEREALE POLLEN	16 [hp_X] in 1 mL
ANTHOXANTHUM ODORATUM POLLEN (UNII: 2KIK19R45Y) (ANTHOXANTHUM ODORATUM POLLEN - UNII:2KIK19R45Y)	ANTHOXANTHUM ODORATUM POLLEN	16 [hp_X] in 1 mL
PASPALUM NOTATUM POLLEN (UNII: V003SHB7VK) (PASPALUM NOTATUM POLLEN - UNII:V003SHB7VK)	PASPALUM NOTATUM POLLEN	16 [hp_X] in 1 mL
QUERCUS ROBUR POLLEN (UNII: 4PNW66TTHR) (QUERCUS ROBUR POLLEN - UNII:4PNW66TTHR)	QUERCUS ROBUR POLLEN	16 [hp_X] in 1 mL
CARYA GLABRA POLLEN (UNII: KPO1Z9N98A) (CARYA GLABRA POLLEN - UNII:KPO1Z9N98A)	CARYA GLABRA POLLEN	16 [hp_X] in 1 mL
PHLEUM PRATENSE POLLEN (UNII: 65M88RW2EG) (PHLEUM PRATENSE TOP - UNII:S7PW24BX20)	PHLEUM PRATENSE POLLEN	16 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)

ALCOHOL (UNII: 3K9958V90M)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43857-0535-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	10/29/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/29/2019	

Labeler - BioActive Nutritional, Inc. (624980496)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43857-0535) , api manufacture(43857-0535) , label(43857-0535) , pack(43857-0535)

Revised: 11/2021

BioActive Nutritional, Inc.