

OSTEOPLEX- equisetum hyemale, magnesia muriatica, ascorbicum acidum, manganum muriaticum, symphytum officinale, medulla ossis suis, calcarea fluorica, calcarea phosphorica, silicea, parathyroid (suis), ligament (human) 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:

Equisetum Hyemale 3X, Magnesia Muriatica 3X, Ascorbicum Acidum 6X, Manganum Muriaticum 6X, Symphytum Officinale 6X, Medulla Ossis Suis 8X, Calcarea Fluorica 12X, Calcarea Phosphorica 12X, Silicea 12X, Parathyroid (Suis) 8C, Ligament (Human) 30C.

INDICATIONS:

For temporary relief of pain in lower part of the back with burning, chronic lower back pain, soreness in the sacroiliac area, pain in the joints & bones.

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 pain in lower part of the back with burning, chronic lower back pain, soreness in the sacroiliac area, pain in the joints & bones.

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
OSTEOPLEX
HOMEOPATHIC
1 FL OZ (30 ml)



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 a cool, dry place.

LOT:

Distributed by:
BioActive Nutritional, Inc.
1803 N. Wickham Rd.
Melbourne, FL 32935
bioactivenutritional.com

OSTEOPLEX
HOMEOPATHIC

ACTIVE INGREDIENTS:
Equisetum Hyemale 3X, Magnesia Muriatica 3X, Ascorbicum Acidum 6X, Manganum Muriaticum 6X, Symphytum Officinale 6X, Medulla Ossis Suis 8X, Calcarea Fluorica 12X, Calcarea Phosphorica 12X, Silicea 12X, Parathyroid Gland 8C, Ligament 30C.

INACTIVE INGREDIENTS:
Demineralized Water,
25% Ethanol

1 FL OZ (30 ml)

INDICATIONS:
For temporary relief of pain in lower part of the back with burning, chronic lower back pain, soreness in the sacroiliac area, pain in the joints & bones.

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

OSTEOPLEX

equisetum hyemale, magnesia muriatica, ascorbicum acidum, manganum muriaticum, symphytum officinale, medulla ossis suis, calcarea fluorica, calcarea phosphorica, silicea, parathyroid (suis), ligament (human) liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43857-0480
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EQUISETUM HYEMALE (UNII: 59677RXH25) (EQUISETUM HYEMALE - UNII:59677RXH25)	EQUISETUM HYEMALE	3 [hp_X] in 1 mL
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	3 [hp_X] in 1 mL
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	6 [hp_X] in 1 mL
MANGANESE CHLORIDE (UNII: QQE170PANO) (MANGANESE CATION (2+) -	MANGANESE CATION (2+)	6 [hp_X]

UNII:H6EP7W5457)	MANGANESE CATION (2+)	in 1 mL
COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	6 [hp_X] in 1 mL
SUS SCROFA BONE MARROW (UNII: VP2CN2G7Y8) (SUS SCROFA BONE MARROW - UNII:VP2CN2G7Y8)	SUS SCROFA BONE MARROW	8 [hp_X] in 1 mL
CALCIUM FLUORIDE (UNII: O3B55K4YKI) (FLUORIDE ION - UNII:Q80VPU408O)	CALCIUM FLUORIDE	12 [hp_X] in 1 mL
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	12 [hp_X] in 1 mL
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	12 [hp_X] in 1 mL
SUS SCROFA PARATHYROID GLAND (UNII: 2KBE35NE8S) (SUS SCROFA PARATHYROID GLAND - UNII:2KBE35NE8S)	SUS SCROFA PARATHYROID GLAND	8 [hp_C] in 1 mL
HUMAN LIGAMENT (UNII: S3Q2347PKA) (HUMAN LIGAMENT - UNII:S3Q2347PKA)	HUMAN LIGAMENT	30 [hp_C] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43857-0480-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/22/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		05/22/2018	

Labeler - BioActive Nutritional, Inc. (624980496)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43857-0480) , api manufacture(43857-0480) , label(43857-0480) , pack(43857-0480)