TINNITUS CONTROL- not applicable liquid
Pacific Naturals

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:

ARNICA MONTANA 30X, CHININUM SULPHURICUM 30X, FERRUM METALLICUM 30X, KALI PHOSPHORICUM 30X, NATRUM SULPHURICUM 30X, PULSATILLA (VULGARIS) 30X, SILICEA 30X, THIOSINAMINUM 30X

INDICATIONS:

Helps relieve symptoms of Tinnitus.

WARNINGS:

If pregnant or breast-feeding, seek the advice of a doctor before use. Do not use if you have ever had an allergic reaction to this product or any of its ingredients. Stop use and ask a doctor if symptoms persist, worsen or if new symptoms occur.

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 around neck of bottle is missing or broken.

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:

Adults and Children over 12: Spray twice under the tongue 3 times per day.

Children under 12: Consult a doctor prior to use.

INDICATIONS:

Helps relieve symptoms of Tinnitus.

INACTIVE INGREDIENTS:

Alcohol 20% v/v, Purified water.

QUESTIONS:

Distributed by:

Pacific Naturals

PO Box 7574

Milton Keynes

MK11 9GQ, United Kingdom

PACKAGE LABEL DISPLAY:

Tinnitus

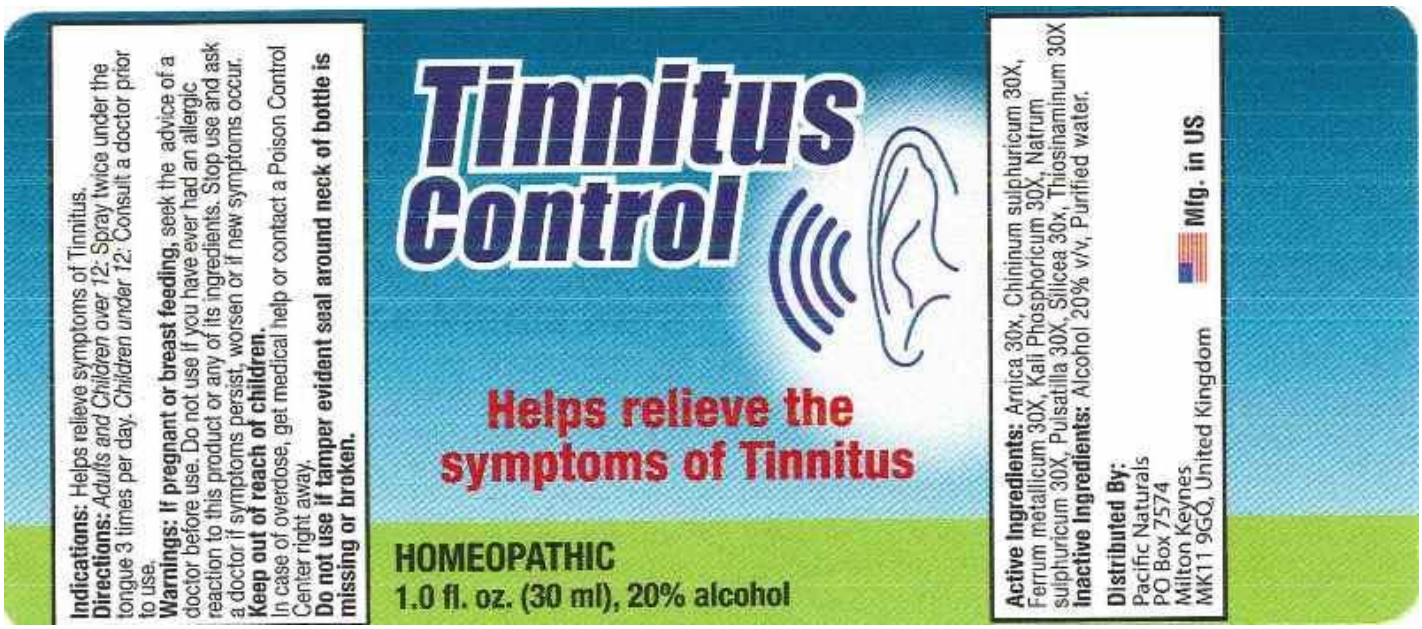
Control

Helps relieve the

symptoms of Tinnitus

HOMEOPATHIC

1.0 fl. oz. (30 ml), 20% alcohol



TINNITUS CONTROL

not applicable liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43695-0009
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	30 [hp_X] in 1 mL
QUININE SULFATE (UNII: KF7Z0E0Q2B) (QUININE - UNII:A7V27PHC7A)	QUININE SULFATE	30 [hp_X] in 1 mL
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	30 [hp_X] in 1 mL
POTASSIUM PHOSPHATE, DIBASIC (UNII: CI71S98N1Z) (PHOSPHATE ION - UNII:NK08V8K8HR)	POTASSIUM PHOSPHATE, DIBASIC	30 [hp_X] in 1 mL
SODIUM SULFATE (UNII: 0YPR65R21J) (SODIUM SULFATE ANHYDROUS -	SODIUM SULFATE	30 [hp_X]

UNII:36KCS0R750)	SODIUM SULFATE	in 1 mL
PULSATILLA VULGARIS (UNII: I76KB35JEV) (PULSATILLA VULGARIS - UNII:I76KB35JEV)	PULSATILLA VULGARIS	30 [hp_X] in 1 mL
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (COLLOIDAL SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	30 [hp_X] in 1 mL
ALLYLTHIOUREA (UNII: 706IDJ14B7) (ALLYLTHIOUREA - UNII:706IDJ14B7)	ALLYLTHIOUREA	30 [hp_X] 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:43695-0009-1	30 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/14/2014	

Labeler - Pacific Naturals (184784283)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43695-0009) , api manufacture(43695-0009) , label(43695-0009) , pack(43695-0009)

Revised: 10/2014 Pacific Naturals