

## **OTITIS MEDIA DROPS 2153- otitis media drops liquid**

### **Professional Complementary Health Formulas**

*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.*

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**C153**

#### **ACTIVE INGREDIENTS**

Calcarea carbonica 3X  
Pulsatilla 4X, 12X, 30X  
Aconitum napellus 6X  
Ear 6X, 60X, 100X, 200X  
Belladonna 12X  
Tellurium metallicum 12X  
Ferrum phosphoricum 12X, 30X  
Gelsemium sempervirens 30X  
Mercurius vivus 30X  
Streptococcus pneumoniae 30X  
Haemophilus influenzae 60X

#### **QUESTIONS**

Professional Formulas

PO Box 2034 Lake Oswego, OR 97035

#### **INDICATIONS**

For the temporary relief of minor earache or ringing in the ears.\*

\*Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

#### **WARNINGS**

Persistent symptoms may be a sign of a serious condition. If symptoms persist or are accompanied by a fever, persistent headache, or loss of hearing, consult a doctor. Keep out of the reach of children. In case of overdose, get medical help or contact a poison control center right away. If pregnant or breastfeeding, ask a healthcare professional before use.

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## DIRECTIONS

Place drops under tongue 30 minutes before/after meals. Adults and children 12 years and over: Take 10 drops up to 3 times per day. Consult a physician for use in children under 12 years of age.

## OTHER INFORMATION

Tamper resistant. If seal is broken, do not use. After opening, close container tightly and store at room temperature away from heat.

## INACTIVE INGREDIENTS

10% ethanol, purified water, 8% vegetable glycerin (from soy).

## LABEL

Est 1985

Professional Formulas

Complementary Health

Otitis Media Drops

Homeopathic Remedy

2 FL. OZ. (59 mL)



## OTITIS MEDIA DROPS 2153

otitis media drops liquid

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63083-2153

**Route of Administration** ORAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>OYSTER SHELL CALCIUM CARBONATE, CRUDE</b> (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	3 [hp_X] in 59 mL
<b>PULSATILLA MONTANA WHOLE</b> (UNII: 24K790T39B) (PULSATILLA MONTANA WHOLE - UNII:24K790T39B)	PULSATILLA MONTANA WHOLE	4 [hp_X] in 59 mL
<b>ACONITUM NAPELLUS WHOLE</b> (UNII: U0NQ8555JD) (ACONITUM NAPELLUS WHOLE - UNII:U0NQ8555JD)	ACONITUM NAPELLUS WHOLE	6 [hp_X] in 59 mL
<b>SUS SCROFA EAR</b> (UNII: 7DX2J287CV) (SUS SCROFA EAR - UNII:7DX2J287CV)	SUS SCROFA EAR	6 [hp_X] in 59 mL
<b>AMARYLLIS BELLADONNA WHOLE</b> (UNII: 11B89M58UN) (AMARYLLIS BELLADONNA WHOLE - UNII:11B89M58UN)	AMARYLLIS BELLADONNA WHOLE	12 [hp_X] in 59 mL
<b>TELLURIUM</b> (UNII: NQA0O090ZJ) (TELLURIUM - UNII:NQA0O090ZJ)	TELLURIUM	12 [hp_X] in 59 mL
<b>FERROSO FERRIC PHOSPHATE</b> (UNII: 91GQH8I5F7) (FERROSO FERRIC PHOSPHATE - UNII:91GQH8I5F7)	FERROSO FERRIC PHOSPHATE	12 [hp_X] in 59 mL
<b>GELSEMIUM SEMPERVIRENS ROOT</b> (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	30 [hp_X] in 59 mL
<b>MERCURY</b> (UNII: FXS1BY2PGL) (MERCURY - UNII:FXS1BY2PGL)	MERCURY	30 [hp_X] in 59 mL
<b>STREPTOCOCCUS PNEUMONIAE</b> (UNII: BT6U234YR2) (STREPTOCOCCUS PNEUMONIAE - UNII:BT6U234YR2)	STREPTOCOCCUS PNEUMONIAE	30 [hp_X] in 59 mL
<b>HAEMOPHILUS INFLUENZAE</b> (UNII: K738E2MB3I) (HAEMOPHILUS INFLUENZAE - UNII:K738E2MB3I)	HAEMOPHILUS INFLUENZAE	60 [hp_X] in 59 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63083-2153-2	59 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	08/15/1985	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		08/15/1984	

**Labeler** - Professional Complementary Health Formulas (167339027)

**Registrant** - Natural Pharmaceutical Manufacturing LLC (015624923)

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## Establishment

Name	Address	ID/FEI	Business Operations
Natural Pharmaceutical Manufacturing LLC		015624923	manufacture(63083-2153)

Revised: 8/2019

Professional Complementary Health Formulas