

**TRAUMEEL - arnica montana root and atropa belladonna and aconitum napellus and hypericum perforatum and calendula officinalis flowering top and matricaria recutita and achillea millefolium and calcium sulfide and comfrey root and bellis perennis and mercurius solubilis and echinacea, unspecified and echinacea purpurea and hamamelis virginiana root bark/stem bark solution/drops**

**Heel 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.*

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## **Traumeel Ear Drops Rx**

### **DESCRIPTION**

Traumeel Ear Drops Rx is a liquid homeopathic drug for otic administration. Each 0.45 ml vial contains **Active Ingredients**: Arnica montana, radix 3X 9.9 mcl, Belladonna 3X 9.9 mcl, Aconitum napellus 3X 9.54 mcl, Hypericum perforatum 3X 2.97 mcl, Calendula officinalis 2X 0.99 mcl, Chamomilla 3X 0.99 mcl, Millefolium 3X 0.99 mcl, Hepar sulphuris calcareum 6X 0.99 mcl, Symphytum officinale 6X 0.99 mcl, Bellis perennis 2X 0.495 mcl, Mercurius solubilis 6X 0.495 mcl, Echinacea 2X 0.247 mcl, Echinacea purpurea 2X 0.247 mcl, Hamamelis virginiana 1X 0.099 mcl **Inactive Ingredients**: Isotonic Sodium Chloride Solution.

### **INDICATIONS AND USAGE**

Traumeel Ear Drops Rx is indicated for the treatment of pain due to inflammation of otitis media and externa.

### **DOSAGE AND ADMINISTRATION**

*Adults and children 6 years and over*: pour contents of 1 vial directly into the affected ear up to 3 times daily. *Infants and children under 6 years*: pour 1/2 of the contents of 1 vial into the affected ear up to 3 times daily.

### **WARNINGS AND PRECAUTIONS**

No harmful or potentially harmful side effects are known. Traumeel ear drops is generally well-tolerated, however if symptoms persist or worsen, discontinue use.

**To report SUSPECTED ADVERSE REACTIONS, contact Heel Inc. at 1.800.920.9203 or [info@heelusa.com](mailto:info@heelusa.com) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)**



## TRAUMEEL

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### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:50 114-7110
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>ARNICA MONTANA ROOT</b> (UNII: MUE8 Y11327) (ARNICA MONTANA ROOT - UNII:MUE8 Y11327)	ARNICA MONTANA ROOT	3 [hp_X] in 0.45 mL
<b>ATROPA BELLADONNA</b> (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	3 [hp_X] in 0.45 mL
<b>ACONITUM NAPELLUS</b> (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	3 [hp_X] in 0.45 mL
<b>HYPERICUM PERFORATUM</b> (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	3 [hp_X] in 0.45 mL
<b>CALENDULA OFFICINALIS FLOWERING TOP</b> (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	2 [hp_X] in 0.45 mL
<b>MATRICARIA RECUTITA</b> (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	3 [hp_X] in 0.45 mL
<b>ACHILLEA MILLEFOLIUM</b> (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM - UNII:2FXJ6SW4PK)	ACHILLEA MILLEFOLIUM	3 [hp_X] in 0.45 mL
<b>CALCIUM SULFIDE</b> (UNII: 1MBW07J51Q) (CALCIUM CATION - UNII:2M83C4R6ZB, SULFIDE ION - UNII:G15I91XETI)	CALCIUM SULFIDE	6 [hp_X] in 0.45 mL
<b>COMFREY ROOT</b> (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	6 [hp_X] in 0.45 mL
<b>BELLIS PERENNIS</b> (UNII: 2HU33I03UY) (BELLIS PERENNIS - UNII:2HU33I03UY)	BELLIS PERENNIS	2 [hp_X] in 0.45 mL
<b>MERCURIUS SOLUBILIS</b> (UNII: 324Y4038G2) (MERCURIUS SOLUBILIS - UNII:324Y4038G2)	MERCURIUS SOLUBILIS	6 [hp_X] in 0.45 mL
<b>ECHINACEA, UNSPECIFIED</b> (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	2 [hp_X] in 0.45 mL
<b>ECHINACEA PURPUREA</b> (UNII: QI7G114Y98) (ECHINACEA PURPUREA - UNII:QI7G114Y98)	ECHINACEA PURPUREA	2 [hp_X] in 0.45 mL
<b>HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK</b> (UNII: T7S323PKJS) (HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK - UNII:T7S323PKJS)	HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK	1 [hp_X] in 0.45 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50 114-7110-1	10 in 1 CARTON		
1		0.45 mL in 1 VIAL, SINGLE-DOSE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		09/30/2002	

**Labeler** - Heel Inc (102783016)

### Establishment

Name	Address	ID/FEI	Business Operations
Holopack-Verpackungstechnik-GmbH		313222457	manufacture

