

**THYREOIDEA COMPOSITUM - lactic acid, l- and viscum album and colchicum autumnale bulb and conium maculatum flowering top and galium aparine and fucus vesiculosus and sedum acre and sempervivum tectorum leaf and adenosine triphosphate and fumaric acid and alpha-ketoglutaric acid and malic acid and sodium diethyloxalacetate and pulsatilla vulgaris and spongia officinalis skeleton, roasted and sus scrofa thyroid and calcium fluoride and sus scrofa umbilical cord and pork liver and sus scrofa bone marrow and sus scrofa spleen injection**  
**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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## **Thyreoida Compositum 2.2ml Injection**

### **DESCRIPTION**

Injection Solution Ingredient Information: Each 2.2ml ampule contains: Sarcosolacticum acidum 3X, Viscum album 3X, Colchicum autumnale 4X, Conium maculatum 4X, Galium aparine 4X, Fucus vesiculosus 6X, Sedum acre 6X, Sempervivum tectorum 6X, ATP Adenosine triphosphate 8X, Fumaricum acidum 8X,  $\alpha$ -Ketoglutaricum acidum 8X, Malicum acidum 8X, Natrum oxalaceticum 8X, Pulsatilla 8X, Spongia tosta 8X, Thyreoida suis 8X, Calcarea fuorica 10X, Funiculus umbilicalis suis 10X, Hepar suis 10X, Medulla ossis suis 10X, Splen suis 10X, Sulphur 10X, Thymus suis 10X, Cortisone aceticum 28X 22mcl each. Inactive ingredient: Sterile isotonic sodium chloride solution.

### **INDICATIONS AND USAGE**

Thyreoida compositum® Injection Solution is indicated for stimulation of the defense system in thyroid dysfunction, connective tissue dysfunction and glandular dysfunction.

### **DOSAGE AND ADMINISTRATION**

The dosage schedules listed below can be used as a general guide for the administration of Thyreoida compositum® Injection Solution. Thyreoida compositum® Injection Solution shows individual differences in clinical response. Therefore, the dosage for each patient should be individualized according to the patient's response to therapy. Adults and children 7 years and older: in acute disorders, 1 ampule per day, otherwise 1 ampule, 1 to 3 times per week IM/SC/IV/ID. Children ages 2 to 6 receive ½ the adult dosage.

Discard unused solution.

Thyreoida compositum® Injection Solution may be administered intravenously, intramuscularly, subcutaneously, or intradermally. The required dose of Thyreoida compositum® Injection Solution is first withdrawn from the ampule into the syringe, and the syringe is then shaken briefly. Thyreoida compositum® Injection Solution should be administered using a narrow gauge needle (e.g. 22 to 30 gauge). Note: Parental drug products like Thyreoida compositum® Injection Solution should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Thyreoida compositum® Injection Solution is a clear, colorless solution. Discolored solutions should be discarded.

### **WARNINGS AND PRECAUTIONS**

If pain persists or worsens, if new symptoms occur, or if redness or swelling is present, the patient should be carefully re-evaluated because these could be signs of a serious condition.  
Pregnancy Category C. Animal reproduction studies have not been conducted with this drug. It is also not known whether this drug can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. This drug should be given to a pregnant woman only if clearly needed.

To report SUSPECTED ADVERSE REACTIONS, contact Heel Inc. at 1.800.920.9203 or info@heelusa.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

## OVERDOASGE

Due to the low concentration of active ingredients in homeopathic preparations such as Thyroidea compositum® Injection Solution, adverse reactions following overdosage are extremely unlikely. However care must be taken not to exceed the recommended dosage.

## CLINICAL PHARMACOLOGY

The exact mechanism of action of Thyroidea compositum® Injection Solution is not fully understood.  
ThyroideaComp\_Inj\_Box.jpg



## THYREOIDEA COMPOSITUM

lactic acid, l- and viscum album and colchicum autumnale bulb and conium maculatum flowering top and galium aparine and fucus vesiculosus and sedum acre and sempervivum tectorum leaf and adenosine triphosphate and fumaric acid and alpha-ketoglutaric acid and malic acid and sodium diethylmalacetate and pulsatilla vulgaris and spongia officinalis skeleton, roasted and sus scrofa thyroid and calcium fluoride and sus scrofa umbilical cord and pork liver and sus scrofa bone marrow and sus scrofa spleen injection

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:50 114-7041
<b>Route of Administration</b>	INTRAMUSCULAR, SUBCUTANEOUS, INTRAVENOUS, INTRADERMAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LACTIC ACID, L-</b> (UNII: F9S9FFU82N) (LACTIC ACID, L- - UNII:F9S9FFU82N)	LACTIC ACID, L-	3 [hp_X] in 2.2 mL
<b>COLCHICUM AUTUMNALE BULB</b> (UNII: 993QHL78E6) (COLCHICUM AUTUMNALE BULB - UNII:993QHL78E6)	COLCHICUM AUTUMNALE BULB	4 [hp_X] in 2.2 mL
<b>CONIUM MACULATUM FLOWERING TOP</b> (UNII: Q28R5GF371) (CONIUM MACULATUM FLOWERING TOP - UNII:Q28R5GF371)	CONIUM MACULATUM FLOWERING TOP	4 [hp_X] in 2.2 mL
<b>GALIUM APARINE</b> (UNII: Z4B6561488) (GALIUM APARINE - UNII:Z4B6561488)	GALIUM APARINE	4 [hp_X] in 2.2 mL
<b>FUCUS VESICULOSUS</b> (UNII: 535G2ABX9M) (FUCUS VESICULOSUS - UNII:535G2ABX9M)	FUCUS VESICULOSUS	6 [hp_X] in 2.2 mL
<b>SEDUM ACRE</b> (UNII: 2496VW6S9J) (SEDUM ACRE - UNII:2496VW6S9J)	SEDUM ACRE	6 [hp_X] in 2.2 mL
<b>SEMPERVIVUM TECTORUM LEAF</b> (UNII: 3DGJ7BUA01) (SEMPERVIVUM TECTORUM LEAF - UNII:3DGJ7BUA01)	SEMPERVIVUM TECTORUM LEAF	6 [hp_X] in 2.2 mL
<b>ADENOSINE TRIPHOSPHATE</b> (UNII: 8L70Q75FXE) (ADENOSINE TRIPHOSPHATE - UNII:8L70Q75FXE)	ADENOSINE TRIPHOSPHATE	8 [hp_X] in 2.2 mL
<b>FUMARIC ACID</b> (UNII: 88XHZ13131) (FUMARIC ACID - UNII:88XHZ13131)	FUMARIC ACID	8 [hp_X] in 2.2 mL
<b>.ALPHA.-KETOGLUTARIC ACID</b> (UNII: 8ID597Z82X) (.ALPHA.-KETOGLUTARIC ACID - UNII:8ID597Z82X)	.ALPHA.-KETOGLUTARIC ACID	8 [hp_X] in 2.2 mL
<b>MALIC ACID</b> (UNII: 817L1N4CKP) (MALIC ACID - UNII:817L1N4CKP)	MALIC ACID	8 [hp_X] in 2.2 mL
<b>SODIUM DIETHYL OXALACETATE</b> (UNII: 6CA025Y4FG) (DIETHYL OXALACETATE - UNII:15S56468G7)	DIETHYL OXALACETATE	8 [hp_X] in 2.2 mL
<b>PULSATILLA VULGARIS</b> (UNII: I76KB35JEV) (PULSATILLA VULGARIS - UNII:I76KB35JEV)	PULSATILLA VULGARIS	8 [hp_X] in 2.2 mL
<b>SPONGIA OFFICINALIS SKELETON, ROASTED</b> (UNII: 1PIP394IID) (SPONGIA OFFICINALIS SKELETON, ROASTED - UNII:1PIP394IID)	SPONGIA OFFICINALIS SKELETON, ROASTED	8 [hp_X] in 2.2 mL
<b>SUS SCROFA THYROID</b> (UNII: 6RV024OAUQ) (SUS SCROFA THYROID - UNII:6RV024OAUQ)	SUS SCROFA THYROID	8 [hp_X] in 2.2 mL
<b>CALCIUM FLUORIDE</b> (UNII: O3B55K4YKI) (CALCIUM FLUORIDE - UNII:O3B55K4YKI)	CALCIUM FLUORIDE	10 [hp_X] in 2.2 mL
<b>SUS SCROFA UMBILICAL CORD</b> (UNII: 118OYG6W3H) (SUS SCROFA UMBILICAL CORD - UNII:118OYG6W3H)	SUS SCROFA UMBILICAL CORD	10 [hp_X] in 2.2 mL
<b>PORK LIVER</b> (UNII: 6EC706HI7F) (PORK LIVER - UNII:6EC706HI7F)	PORK LIVER	10 [hp_X] in 2.2 mL
<b>SUS SCROFA BONE MARROW</b> (UNII: VP2CN2G7Y8) (SUS SCROFA BONE MARROW - UNII:VP2CN2G7Y8)	SUS SCROFA BONE MARROW	10 [hp_X] in 2.2 mL

<b>SUS SCROFA SPLEEN</b> (UNII: 92AMN5J79Y) (SUS SCROFA SPLEEN - UNII:92AMN5J79Y)	SUS SCROFA SPLEEN	10 [hp_X] in 2.2 mL
<b>SULFUR</b> (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	10 [hp_X] in 2.2 mL
<b>SUS SCROFA THYMUS</b> (UNII: 7B69B0BD62) (SUS SCROFA THYMUS - UNII:7B69B0BD62)	SUS SCROFA THYMUS	10 [hp_X] in 2.2 mL
<b>VISCUM ALBUM FRUIT</b> (UNII: P83EQ521R3) (VISCUM ALBUM FRUIT - UNII:P83EQ521R3)	VISCUM ALBUM FRUIT	3 [hp_X] in 2.2 mL
<b>CORTISONE ACETATE</b> (UNII: 883WKN7W8X) (CORTISONE - UNII:V27W9254FZ)	CORTISONE	28 [hp_X] in 2.2 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50 114-7041-1	10 in 1 CARTON		
1		2.2 mL in 1 AMPULE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/08/2011	

**Labeler** - Heel Inc (102783016)

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Heel Inc