

**ITIRES- arnica montana root, calcium fluoride, calcium iodide, clematis recta flowering top, scrophularia nodosa, conium maculatum flowering top, horse chestnut, and hedera helix flowering twig ointment**  
**PEKANA Naturheilmittel GmbH**

*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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**ITIRES™**

**Drug facts**

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**Active ingredients**

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Aesculus hippocastanum	4X
Arnica montana	8X
Calcium fluoratum	8X
Calcium jodatum	6X
Clematis recta	4X
Conium maculatum	6X
Hedera helix	6X
Scrophularia nodosa	2X

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Selected ingredients prepared by spagyric processes.

**Uses<sup>1</sup>**

Helps cleanse and detoxify the body

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<sup>1</sup> Application of this homeopathic remedy for the designated usage is exclusively based on homeopathic experience. These "Uses" have not been evaluated by the Food and Drug Administration. With severe forms of this disease, a clinically proven therapy is indicated.

**Warnings**

For external use only. Do not use on open wounds! If symptoms persist, contact a licensed practitioner. If you have known sensitivity to any of the ingredients, please consult your licensed practitioner before use. If you are pregnant or nursing a baby, seek the advice of a health care professional before use.

Keep out of the reach of children.

**Directions**

Unless otherwise prescribed, apply a moderate amount of ointment 2 to 3 times per day by rubbing gently into the affected area.

**Other information**

Protect from light and heat.

**Tamper Evident**

Do not use this product if tamper evident strip is broken or removed from base of cap.

**Inactive ingredients**

Purified water, cetyl alcohol, cetylstearyl alcohol, glycerol, synthetic cetaceum, triglycerides.

**Manufactured by:**

PEKANA® GmbH  
D-88353 Kisslegg

**Distributed by:**

BioResource Inc.  
Cotati, CA 94931

**PRINCIPAL DISPLAY PANEL - 35 g Tube Box**

PEKANA®

ITIRES™  
Homeopathic Ointment

Helps cleanse and detoxify the body

1.2 OZ  
35 g

NDC-Code: 59469-309-35



PEKANA®

# ITIRES™

Homeopathic Ointment

Helps cleanse and detoxify the body

1.2 OZ  
35 g

### Drug facts continued

#### Other information

Protect from light and heat.  
Tamper Evident: Do not use this product if tamper evident strip is broken or removed from base of cap.

#### Inactive ingredients

Purified water, oily alcohol, cetylstearyl alcohol, glycerol, synthetic cetylalcaurum, triglycerides.

\* Application of this homeopathic remedy for the designated usage is exclusively based on homeopathic experience. These "Uses" have not been evaluated by the Food and Drug Administration. With severe forms of this disease, a clinically proven therapy is indicated.

#### Manufactured by:

PEKANA® GmbH  
D-88353 Kisslegg

#### Distributed by:

BioResource Inc.  
Cotati, CA 94931  
Made in Germany

To report adverse events, contact BioResource at 321B Blodgett Street, Cotati, CA 94931

### Drug facts

#### Active ingredients

Aesculus	4X
hippocastanum	8X
Arnica montana	8X
Calcium fluoratum	6X
Calcium iodatum	4X
Chamomilla recta	6X
Conium maculatum	6X
Hedera helix	6X
Scrophularia nodosa	2X

Selected ingredients prepared by spagyric processes.

#### Uses\*

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#### Warnings

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#### Directions

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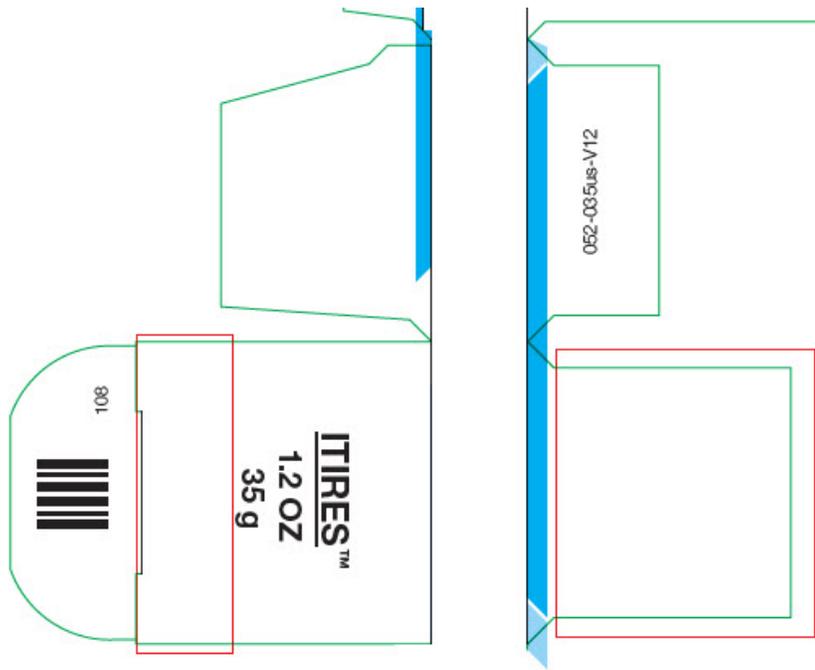
PEKANA®

ITIRES™

1.2 OZ  
35 g



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## ITIRES

arnica montana root, calcium fluoride, calcium iodide, clematis recta flowering top, scrophularia nodosa, conium maculatum flowering top, horse chestnut, and hedera helix flowering twig ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59469-309
<b>Route of Administration</b>	CUTANEOUS		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Arnica montana Root</b> (UNII: MUE8Y11327) (Arnica montana Root - UNII:MUE8Y11327)	Arnica montana Root	8 [hp_X] in 35 g
<b>CALCIUM FLUORIDE</b> (UNII: Q3B55K4YKI) (FLUORIDE ION - UNII:Q80VPU4080)	CALCIUM FLUORIDE	8 [hp_X] in 35 g
<b>CALCIUM IODIDE</b> (UNII: 8EKI9QEE2H) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM IODIDE	6 [hp_X] in 35 g
<b>Clematis recta Flowering Top</b> (UNII: 396421SP9F) (Clematis recta Flowering Top - UNII:396421SP9F)	Clematis recta Flowering Top	4 [hp_X] in 35 g
<b>SCROPHULARIA NODOSA WHOLE</b> (UNII: 7H443NUB2T) (SCROPHULARIA NODOSA WHOLE - UNII:7H443NUB2T)	SCROPHULARIA NODOSA WHOLE	2 [hp_X] in 35 g
<b>Conium maculatum Flowering Top</b> (UNII: Q28R5GF371) (Conium maculatum Flowering Top - UNII:Q28R5GF371)	Conium maculatum Flowering Top	6 [hp_X] in 35 g
<b>HORSE CHESTNUT</b> (UNII: 3C18L6RJAZ) (HORSE CHESTNUT - UNII:3C18L6RJAZ)	HORSE CHESTNUT	4 [hp_X] in 35 g
<b>Hedera helix Flowering Twig</b> (UNII: 3D10KUA6BM) (Hedera helix Flowering Twig - UNII:3D10KUA6BM)	Hedera helix Flowering Twig	6 [hp_X] in 35 g

### Inactive Ingredients

Ingredient Name	Strength
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>Cetyl Alcohol</b> (UNII: 936JST6JCN)	
<b>SPERMACETI</b> (UNII: P86KHA8V3K)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>Alcohol</b> (UNII: 3K9958V90M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59469-309-35	1 in 1 BOX	06/24/2019	
1		35 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:59469-309-30	1 in 1 BOX	06/24/2019	
2		30 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved homeopathic		06/24/2019	

**Labeler** - PEKANA Naturheilmittel GmbH (320344542)

### Establishment

Name	Address	ID/FEI	Business Operations
PEKANA Naturheilmittel GmbH		320344542	MANUFACTURE(59469-309)

Revised: 12/2022

PEKANA Naturheilmittel GmbH