

**CHILDRENS EARACHE RELIEF- chamomilla 10x, mercurius solubilis 15x,
pulsatilla 12x, sulphur 12x solution
Similasan Corporation**

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.

Childrens Earache Relief

Drug Facts - Children's Earache Relief

Active ingredients

Chamomilla 10X

Mercurius solubilis 15X

Pulsatilla 12X

Sulphur 12X

Purpose

sensitivity to drafts, soothing

fullness, sensitivity to cold

night time calmative

itchiness, sensitivity to water

Uses*

According to homeopathic principles, the active ingredients in this product temporarily relieve earache symptoms such as:

- sensation of fullness of the ear
- sensitivity to cold, drafts, and water
- the annoyance of water-clogged ears by helping clear water trapped in the ear

Warnings

- **Do not use** in the eyes.

Children under 2 years of age should be seen by a physician.

- According to homeopathic principles, symptoms may temporarily worsen before improving (Initial exacerbation of symptoms).

If pregnant, trying to get pregnant or breast feeding,

ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if:

- symptoms persist for more than 48 hours
- there is discharge from the ear
- there is a fever of 102°F or greater

Ask a doctor before use if the child has:

- ear drainage or discharge
- pain, irritation, or rash in the ear
- had ear surgery
- dizziness

Directions

FOR USE IN THE EAR ONLY.

For children ages 2 and over:

- Remove tamper-evident seal from neck of bottle.
- Twist cap off bottle.
- Tilt child's head sideways.
- **DON'T** squeeze bottle, squeeze plastic tip to release 3-5 drops into ear (tip of applicator should not enter ear canal).
- Keep drops in ear for 3-5 minutes by keeping head tilted or placing cotton in ear. Any excess drops can be wiped away from outer ear.
- Use up to 4 times daily for no more than 48 hours, or as directed by a doctor.

Other information

Active ingredients are manufactured according to homeopathic principles.

Inactive ingredient

Purified water, Vegetable glycerin

Questions?

Reach our representatives at **1-800-240-9780** or getinfo@similasanusa.com

www.SimilasanUSA.com

PRINCIPAL DISPLAY PANEL

NDC 59262-274-11

Similasan









Children's

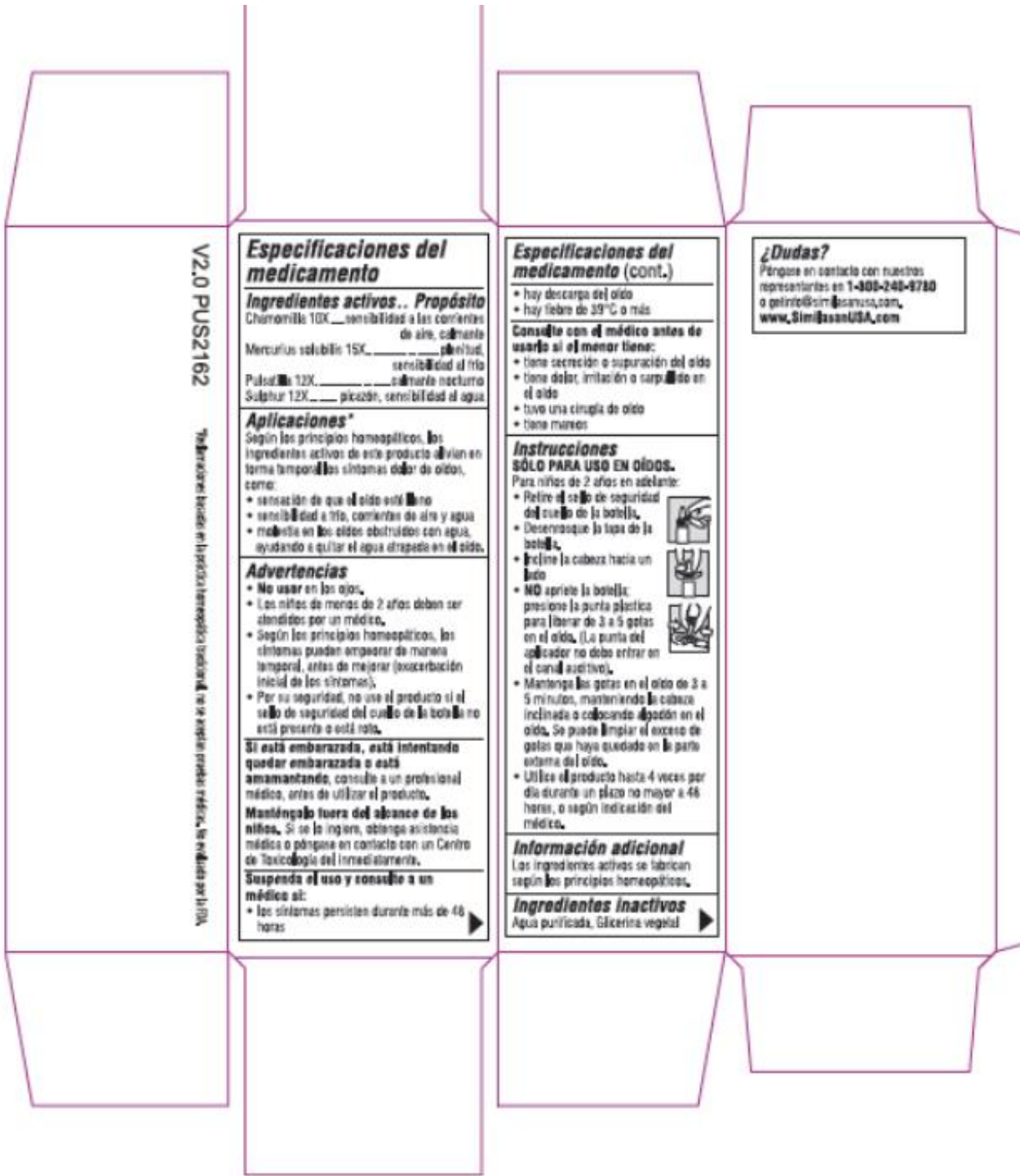
Earache

Relief

EAR DROPS

10 ml / 0.33 fl oz

<p>unpainted/uncoated area Farb/Lackausparung</p>		 <p>Children's Earache Relief™ NATURAL ACTIVE INGREDIENTS</p> 	
<p>Drug Facts Active Ingredients ... Purpose Chamonix 10X... sensitivity to drafts, soothng Mercurus solubilis 15X... hness, Pulsatilla 12X... sensitivity to cold, right time calative Sulphur 12X... itiness, sensitivity to water</p> <p>Uses* According to homeopathic principles, the active ingredients in this product temporarily relieve earache symptoms such as: • sensation of fullness of the ear • sensitivity to cold, drafts and water • the annoyance of water-clogged ears by helping clear water trapped in the ear</p> <p>Warnings • Do not use in the eyes. • Children under 2 years of age should be seen by a physician. • According to homeopathic principles, symptoms may temporarily worsen before improving (initial exacerbation of symptoms).</p> <p>If pregnant, trying to get pregnant or breast feeding, ask a health professional before use.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Stop use and ask a doctor if: • symptoms persist for more than 48 hours • there is discharge from the ear • there is a fever of 102°F or greater</p>	<p>Drug Facts (continued) Ask a doctor before use if the child has: • ear drainage or discharge • pain, irritation, or rash in the ear • had ear surgery • dizziness</p> <p>Directions FOR USE IN THE EAR ONLY. For children ages 2 and over: • Remove tamper-evident seal from neck of bottle. • Twist cap off bottle. • Tilt child's head sideways. • DON'T squeeze bottle, squeeze plastic tip to release 3-5 drops into ear (tip of applicator should not enter ear canal). • Keep drops in ear for 3-5 minutes by keeping head tilted or placing cotton in ear. Any excess drops can be wiped away from outer ear. • Use up to 4 times daily for no more than 48 hours, or as directed by a doctor.</p> <p>Other information Active ingredients are manufactured according to homeopathic principles.</p> <p>Inactive ingredients Purified water, Vegetable Glycerin</p> <p>Questions? Reach our representatives at 1-800-240-9780 or getinfo@similasanusa.com or www.SimilasanUSA.com</p>	 <p>Children's Earache Relief™ EAR DROPS</p> <p>HELPS RELIEVE DISCOMFORT FROM • Cold & Drafts • Clogged Ears • Trapped Water</p>  <p>NATURAL ACTIVE INGREDIENTS</p>	<p>Alivio de Dolor de Oído en Niños Cura para los niños</p> <p>INGREDIENTES ACTIVOS NATURALES AYUDA A ALIVIAR EL DOLOR CAUSADO POR • Resfriados y corrientes de aire • Oídos tapados • Agua atrapada</p> <p><i>Instrucciones en español adentro</i></p> <p>Similasan, trusted for over 40 years in Switzerland, No Harsh Chemicals</p> <p><small>Similasan and Similasan Children's Earache Relief are trademarks of The Eye Care Management AG, Switzerland, and the Similasan logo is a registered trademark of The Eye Care Management AG, Switzerland. Manufactured by Similasan AG, 4904 Jona, Switzerland. Imported and Distributed by Similasan Corporation, Highlands Ranch, CO 80129. Made in Switzerland.</small></p> <p>www.SimilasanUSA.com</p>
<p>*Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.</p>	<p>For your protection do not use if tamper evident seal around neck of bottle is missing or broken.</p>	<p>HOMEOPATHIC Original Swiss Formula 10 ml / 0.33 fl oz</p> 	<p>Feel Good About Feeling Better™</p>
<p>unpainted/uncoated area Farb/Lackausparung</p>	<p>V2.0 PUS2162</p>	<p>NDC 59262-274-11</p>  <p>0 94841 91003 1</p>	
<p>unpainted/uncoated area Farb/Lackausparung</p>		<p>unpainted/uncoated area Farb/Lackausparung</p>	<p>Space (at minimum 7mm) EXP. and batch</p>



CHILDRENS EARACHE RELIEF

chamomilla 10x, mercurius solubilis 15x, pulsatilla 12x, sulphur 12x solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59262-274
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety

Base of

Ingredient Name	Basis of Strength	Strength
CHAMOMILE (UNII: FGL3685T2X) (CHAMOMILE - UNII:FGL3685T2X)	CHAMOMILE	10 [hp_X] in 10 mL
MERCURIUS SOLUBILIS (UNII: 324Y4038G2) (MERCURIUS SOLUBILIS - UNII:324Y4038G2)	MERCURIUS SOLUBILIS	15 [hp_X] in 10 mL
PULSATILLA PATENS WHOLE (UNII: 4M1169RWJD) (PULSATILLA PATENS WHOLE - UNII:4M1169RWJD)	PULSATILLA PATENS WHOLE	12 [hp_X] in 10 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [hp_X] in 10 mL

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59262-274-11	10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	01/01/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/01/2007	

Labeler - Similasan Corporation (111566530)

Revised: 4/2021

Similasan Corporation