

**KIDS EARACHE RELIEF- matricaria recutita, mercurius solubilis, anemone patens and sulphur 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.*

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**Kids Earache Relief**

**Drug Facts - Kids 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.
- 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 4-5 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**

Vegetable glycerin

**Questions?**

Reach our representatives at **1-800-240-9780** or [getinfo@similasanusa.com](mailto:getinfo@similasanusa.com)

**www.SimilasanUSA.com**

**PRINCIPAL DISPLAY PANEL**

NDC 59262-276-11

Similasan






Kids

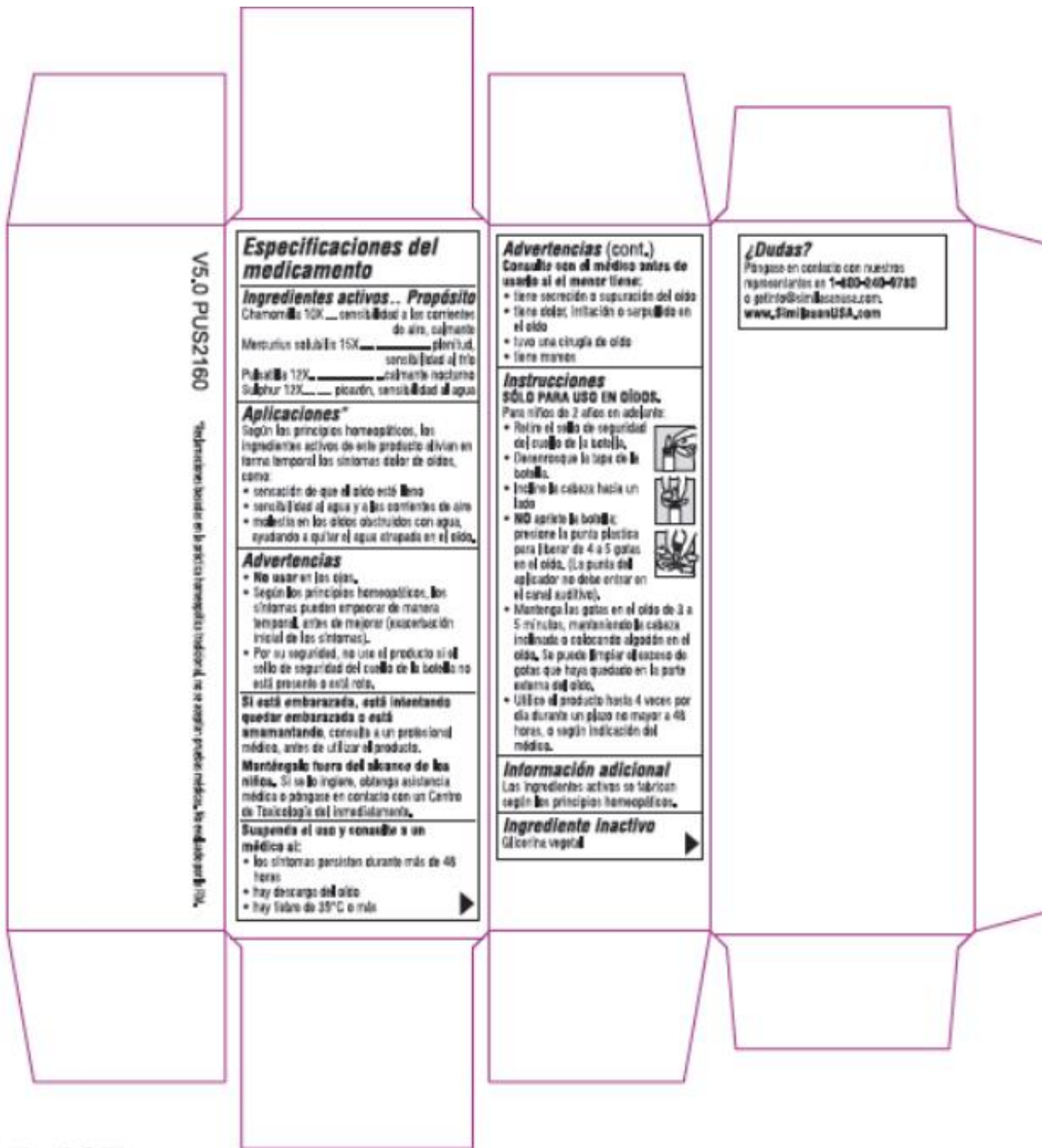
Earache

Relief

EAR DROPS

10 ml / 0.33 fl oz

<p>unprinted/uncoated area Farb/Lackausparung 23.4 mm x 11.7 mm</p>			
<p><b>Drug Facts</b> <b>Active ingredients</b> ... Purpose Chininum 10X _____ sensitivity to drafts, _____ soothing Mercurius solubilis 15X _____ fullness, _____ sensitivity to cold Pulsatilla 12X _____ night time earaches Sulphur 12X _____ itchiness, _____ sensitivity to water</p>	<p><b>Drug Facts (continued)</b> <b>Directions (cont.)</b></p> <ul style="list-style-type: none"> <li>Remove larger evident seal from neck of bottle.</li> <li>Twist cap off bottle.</li> <li>Tip child's head sideways.</li> <li><b>DON'T</b> squeeze bottle, squeeze plastic tip to release 4-5 drops into ear (tip of applicator should not enter ear canal).</li> <li>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.</li> <li>Use up to 4 times daily for no more than 48 hours, or as directed by a doctor.</li> </ul>	<p>NDC 59262-276-11</p> 	<p><b>Alivio de dolor de oído en niños</b> <b>ES</b> <i>Alivio para los niños</i> <b>Formulado Con INGREDIENTES ACTIVOS NATURALES</b> <b>AYUDA A ALIVAR LA INCOMODIDAD DE</b></p> <ul style="list-style-type: none"> <li>Resaca y corrientes de aire</li> <li>Oídos tapados</li> <li>Aguá atrapada</li> </ul> <p><i>Indicaciones en español adentro</i></p>
<p><b>Uses*</b> According to homeopathic principles, the active ingredients in this product temporarily relieve earache symptoms such as:</p> <ul style="list-style-type: none"> <li>sensation of fullness of the ear</li> <li>sensitivity to water and drafts</li> <li>the annoyance of water-clogged ears by helping clear water trapped in the ear</li> </ul>	<p><b>Other information</b> Active ingredients are manufactured according to homeopathic principles.</p>	<p><b>Kids Earache Relief</b> EAR DROPS</p> 	<p>Similasan works differently than most medicated products, formulated with natural active ingredients and tested for over 35 years in Switzerland. It gently stimulates your body's natural ability to temporarily relieve symptoms.</p>
<p><b>Warnings</b></p> <ul style="list-style-type: none"> <li>Do not use in the eyes.</li> <li>According to homeopathic principles, symptoms may temporarily worsen before improving (initial exacerbation of symptoms).</li> </ul>	<p><b>Inactive ingredient</b> Vegetable Glycerin</p>	<p>Formulated With NATURAL ACTIVE INGREDIENTS</p> <p><b>HELPS RELIEVE DISCOMFORT FROM</b></p> <ul style="list-style-type: none"> <li>Colds &amp; Drafts</li> <li>Clogged Ears</li> <li>Trapped Water</li> </ul> <p>AGES 2+ <i>Español</i> →</p>	<p><a href="http://www.SimilasanUSA.com">www.SimilasanUSA.com</a></p> 
<p><b>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</b></p>	<p><b>Questions?</b> Reach our representatives at <b>1-800-240-9780</b> or <a href="mailto:getinfo@similasanusa.com">getinfo@similasanusa.com</a> or <a href="http://www.SimilasanUSA.com">www.SimilasanUSA.com</a></p>	<p><b>HOMEOPATHIC</b> Original Swiss Formula 10 ml / 0.33 fl oz</p>	<p><b>Feel Good About Feeling Better™</b></p>
<p><b>Stop use and ask a doctor if:</b></p> <ul style="list-style-type: none"> <li>symptoms persist for more than 48 hours</li> <li>there is discharge from the ear</li> <li>there is a fever of 102°F or greater</li> </ul> <p><b>Ask a doctor before use if the child has:</b></p> <ul style="list-style-type: none"> <li>ear drainage or discharge</li> <li>pain, irritation, or rash in the ear</li> <li>had ear surgery</li> <li>diarrhea</li> </ul>	<p>For your protection do not use if larger evident seal around neck of bottle is missing or broken.</p> <p>*Claims based on traditional homeopathic practice, not accepted medical evidence, Not FDA evaluated.</p>	<p>Similasan is a trademark of Similasan AG, Switzerland, and the Similasan logo is a registered trademark of Similasan AG, Switzerland. Manufactured by: Similasan AG, Switzerland Imported and Distributed by: Similasan Corporation, Highlands Ranch, CO 80129 1-800-240-9780 Made in Switzerland</p>	<p>V5.0 PUS2160</p>
<p>unprinted/uncoated area Farb/Lackausparung 23.4 mm x 17.3 mm</p>	<p>Follow us for special offers</p> 	<p>unprinted/uncoated area Farb/Lackausparung</p>	<p>Space (at minimum 7mm EXP. and batch</p>



<b>KIDS EARACHE RELIEF</b>			
matricaria recutita, mercurius solubilis, anemone patens and sulphur solution			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59262-276
<b>Route of Administration</b>	AURICULAR (OTIC)		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name	Basis of Strength	Strength	
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA -	MATRICARIA	10 [hp_X]	

UNII:G0R4UBI2ZZ)	CHAMOMILLA	in 10 mL
<b>MERCURIUS SOLUBILIS</b> (UNII: 324Y4038G2) (MERCURIUS SOLUBILIS - UNII:324Y4038G2)	MERCURIUS SOLUBILIS	15 [hp_X] in 10 mL
<b>PULSATILLA PATENS WHOLE</b> (UNII: 4M1169RWJD) (PULSATILLA PATENS WHOLE - UNII:4M1169RWJD)	PULSATILLA PATENS WHOLE	12 [hp_X] in 10 mL
<b>SULFUR</b> (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [hp_X] in 10 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59262-276-11	1 in 1 BOX	07/20/2018	
1		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/20/2018	

**Labeler** - Similasan Corporation (111566530)

Revised: 10/2021

Similasan Corporation