

**DRY EYE RELIEF- atropa belladonna and euphrasia stricta and mercuric chloride solution/
drops**

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.

Similasan Dry Eye Relief Trial Size

Active Ingredient

Belladonna* 6X

*containing 0.000002% alkaloids calculated as hyoscyamine.

Purpose

dryness, redness

Active Ingredient

Euphrasia 6X

Purpose

redness

Active Ingredient

Mercurius sublimatus 6X

Purpose

dryness

Uses

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

- dry eye
- redness of eyes and lids
- reflex watering secondary to dry eye
- sensation of grittiness
- sensitivity to light

Warnings

- **For external use only.**
- Initial exacerbation of symptoms may occur.
- Use only if single-use dropper is intact.
- To avoid contamination, do not touch the tip of the dropper to any surface. Do not reuse. Once opened, discard.

- Contact wearers: consult a physician prior to using.

Do not use:

if the solution changes color or becomes cloudy

Stop use and ask a doctor if:

- symptoms worsen or persist for more than 72 hours.
- changes in vision occur.
- you experience eye pain.

If 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.

Directions

For adults and children age 2 and over:

- remove a single-use dropper
- twist flat end with ball to remove
- squeeze plastic dropper to release 2-3 drops into eye and discard applicator

Inactive Ingredients

Phosphate buffer, Purified water

Principal Display Panel

NDC 59262-352-13

Similasan

Dry Eye

Relief

SINGLE-USE STERILE EYE DROPS

Preservative Free

0.4 ml/ 0.014 fl oz each

	<p>V8.0 PUS0975</p> <p>0</p>  <p>94841300115</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 Made in Switzerland</p> <p>Coupon Inside!</p> <p><i>Instrucciones en español adentro</i></p> <p>www.SimilasanUSA.com 1-800-240-9780</p> <p>*These statements are based upon traditional homeopathic principles. They have not been reviewed by the Food and Drug Administration</p> <p>For your protection do not use if single-use dropper is broken or damaged.</p>	<p>NDC 59262-352-13</p>  <p>Dry Eye Relief™</p> <p>SINGLE-USE STERILE EYE DROPS</p> <p>PRESERVATIVE FREE</p> <p>Formulated With NATURAL ACTIVE INGREDIENTS</p> <p>USE AS OFTEN AS NEEDED</p> <ul style="list-style-type: none"> • Dryness • Redness • Soothes • Moisturizes <p>HOMEOPATHIC Original Swiss Formula</p> <p>0.4 ml / 0.014 fl oz (one vial)</p>  <p>NO HARSH VASOCONSTRICTORS</p>	<table border="1"> <tr> <td colspan="2">Drug Facts</td> </tr> <tr> <td>Active Ingredients</td> <td>Purpose</td> </tr> <tr> <td>Belladonna' 6X.....</td> <td>dryness, redness</td> </tr> <tr> <td>Euphrasia officinalis (Eyebright) 6X.....</td> <td>redness</td> </tr> <tr> <td>Mercurius sublimatus 6X.....</td> <td>dryness</td> </tr> <tr> <td colspan="2">Uses* According to homeopathic principles, the active ingredients in this product temporarily relieve minor symptoms such as:</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> • dry eye • redness of eyes and lids • reflex watering secondary to dry eye </td> </tr> <tr> <td colspan="2">Warnings • For external use only.</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> • According to homeopathic principles, symptoms may temporarily worsen before improving (Initial exacerbation of symptoms). • Use only if single-use dropper is intact. • To avoid contamination, do not touch the tip of the dropper to any surface. Do not reuse. Once opened, discard. • Contact wearers: consult a physician prior to using. </td> </tr> <tr> <td colspan="2">If pregnant, trying to get pregnant or breast feeding, ask a health professional before use.</td> </tr> <tr> <td colspan="2">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</td> </tr> <tr> <td colspan="2">Do not use: if the solution changes color or becomes cloudy</td> </tr> <tr> <td colspan="2">Stop use and ask a doctor if: <ul style="list-style-type: none"> • symptoms worsen or persist for more than 72 hours • you experience eye pain or changes in vision </td> </tr> <tr> <td colspan="2">Directions For adults and children age 2 and over: <ul style="list-style-type: none"> • remove single-use dropper • twist flat end with ball to open • squeeze plastic dropper to release 2-3 drops into eye and discard applicator </td> </tr> <tr> <td colspan="2">Inactive Ingredients Phosphate buffer, Purified water</td> </tr> <tr> <td colspan="2">containing 0.000002% alkaloids calculated as hyoscyamine</td> </tr> <tr> <td colspan="2" style="text-align: center;">COMPLETE DRUG FACTS INSIDE</td> </tr> </table>	Drug Facts		Active Ingredients	Purpose	Belladonna' 6X.....	dryness, redness	Euphrasia officinalis (Eyebright) 6X.....	redness	Mercurius sublimatus 6X.....	dryness	Uses* According to homeopathic principles, the active ingredients in this product temporarily relieve minor symptoms such as:		<ul style="list-style-type: none"> • dry eye • redness of eyes and lids • reflex watering secondary to dry eye 		Warnings • For external use only.		<ul style="list-style-type: none"> • According to homeopathic principles, symptoms may temporarily worsen before improving (Initial exacerbation of symptoms). • Use only if single-use dropper is intact. • To avoid contamination, do not touch the tip of the dropper to any surface. Do not reuse. Once opened, discard. • Contact wearers: consult a physician prior to using. 		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.		Do not use: if the solution changes color or becomes cloudy		Stop use and ask a doctor if: <ul style="list-style-type: none"> • symptoms worsen or persist for more than 72 hours • you experience eye pain or changes in vision 		Directions For adults and children age 2 and over: <ul style="list-style-type: none"> • remove single-use dropper • twist flat end with ball to open • squeeze plastic dropper to release 2-3 drops into eye and discard applicator 		Inactive Ingredients Phosphate buffer, Purified water		containing 0.000002% alkaloids calculated as hyoscyamine		COMPLETE DRUG FACTS INSIDE	
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Principal Display Panel

SIMILASAN / USA

30011

Dry Eye Relief, eye drops

270 pieces(Stk)

SIMILASAN / USA

30011

Dry Eye Relief, eye drops
2 x 0.45 ml, 2 Single Use
Droppers, Trial size buffered

270 pieces (Stk.)

Batch

00000

Exp.

12/2008

WUS0975 Augentropfen Nr.1 PU, 2 Monodosen

Checked by: _____



60094841300117

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Dry Eye Relief, eye drops
2 x 0.45 ml, 2 Single Use
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Checked by: _____



60094841300117

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59262-352
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	6 [hp_X] in 0.4 mL
EUPHRASIA STRICTA (UNII: C9642I91WL) (EUPHRASIA STRICTA - UNII:C9642I91WL)	EUPHRASIA STRICTA	6 [hp_X] in 0.4 mL
MERCURIC CHLORIDE (UNII: 53GH7MZT1R) (MERCURIC CATION - UNII:ED30FJ8Y42)	MERCURIC CHLORIDE	6 [hp_X] in 0.4 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59262-352-01	270 in 1 CARTON	07/02/2013	
1		0.4 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		
2	NDC:59262-352-13	.4 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product	07/02/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED HOMEOPATHIC		07/02/2013	

Labeler - Similasan Corporation (111566530)

Establishment

Name	Address	ID/FEI	Business Operations
International Packaging Inc		071493142	REPACK(59262-352)