

BABY GUM RELIEF- calcium fluoride, chamomile, ferrum phosphoricum, oyster shell calcium carbonate, crude, podophyllum and tribasic calcium phosphate tablet, orally disintegrating
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.

BABY GUM RELIEF

Drug Facts

| Active Ingredients | Purpose |
|--------------------------------------|--|
| Calcarea carbonica (Calcium) 12X | pain, difficult dentition |
| Calcarea fluorica (Calcium) 12X | supports dental development |
| Calcarea phosphorica (Calcium) 12X | supports dental development, pain, slow dentition |
| Chamomilla (Chamomile) 8X | swelling, irritability, restlessness, sleeplessness, red cheek/face |
| Ferrum phosphoricum 12X | pain |
| Podophyllum peltatum (May Apple) 12X | drooling, chewing on things, irritability, fussiness or restlessness |

Uses¹

According to homeopathic principles, the active ingredients in this product:

- temporarily relieve restlessness & irritability due to painful gums
- support dental development

¹ Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

Warnings

- According to homeopathic principles, symptoms may temporarily worsen before improving (Initial exacerbation of symptoms).
- Do not use this product for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve in 7 days; if irritation, pain, or redness persists or worsens; or if swelling, rash, or fever develops, see your dentist or doctor promptly.
- Do not exceed recommended dosage.
- As with all medications, it is important to ensure that your child's medical professional is aware of the use of this product.

Keep out of reach of children. In case of accidental overdose, contact a medical professional or a poison control center immediately.

Directions

Dissolve 1 tablet on tongue up to every 15 minutes for up to 12 doses per day.

Other information

Active ingredients are manufactured according to homeopathic principles.

Do not use if tamper evident seal beneath cap is broken or missing.

For more information, see <http://www.similasanUSA.com/about-homeopathy>

Inactive ingredients

Crospovidone, Mannitol, Sodium stearyl fumarate

Questions?

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

Distributed by:

Similasan Corp., Highlands Ranch, CO 80129

PRINCIPAL DISPLAY PANEL - 135 Tablet Bottle Box

NDC 59262-502-26

BELLADONNA

FREE

Similasan®

Baby Gum

Relief

QUICK DISSOLVING TABLETS

Formulated with

NATURAL ACTIVE INGREDIENTS

BABY

- Chamomile for Irritability*
- Triple Calcium Blend Supports
Development of Healthy Teeth*
- Benzocaine Free • Belladonna Free

HOMEOPATHIC

The Swiss Original

135 Quick Dissolving
Tablets (actual size)

Similasan.

Baby Gum Relief

QUICK DISSOLVING TABLETS

Formulated with **NATURAL ACTIVE INGREDIENTS**

NDC 59262-502-26

**BELLADONNA
FREE**



Similasan.

Similasan® **Baby Gum Relief** is a remedy for painful gums with Triple Calcium Blend that also supports the development of healthy teeth. All without harsh chemicals or Belladonna.

Formulated with natural active **Chamomile** and **Triple Calcium Blend**.

Alivio para las encías del bebé

ES
Español

Tabletas de disolución rápida

Formulado con Ingredientes Activos Naturales

- Manzanilla para la irritabilidad*
- La mezcla de calcio triple apoya el desarrollo de dientes sanos*
- Libre de benzocaína
- Libre de belladona

Instrucciones en español adentro

Similasan works differently than most medicated products. Formulated with natural active ingredients and trusted for over 35 years in Switzerland, it gently stimulates the body's natural ability to temporarily relieve symptoms.

Baby Gum Relief

QUICK DISSOLVING TABLETS



BABY

No artificial flavors, dyes, sweeteners, parabens, preservatives, gluten, dairy, or belladonna

www.SimilasanUSA.com

Formulated with **NATURAL ACTIVE INGREDIENTS**

- **Chamomile for Irritability***
- **Triple Calcium Blend Supports Development of Healthy Teeth***
- **Benzocaine Free • Belladonna Free**

Español ▶

* Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

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HOMEOPATHIC
The Swiss Original



135 Quick Dissolving Tablets (actual size)

V7.0 PUS2285

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Similasan Corp., Highlands Ranch, CO 80129
1-800-240-9780
Made in USA

unpainted/uncoated area

BABY GUM RELIEF

calcium fluoride, chamomile, ferrum phosphoricum, oyster shell calcium carbonate, crude, podophyllum and tribasic calcium phosphate tablet, orally disintegrating

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:59262-502 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------------------|-----------------|
| OYSTER SHELL CALCIUM CARBONATE, CRUDE (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I) | OYSTER SHELL CALCIUM CARBONATE, CRUDE | 12 [hp_X] |
| CALCIUM FLUORIDE (UNII: O3B55K4YKI) (FLUORIDE ION - UNII:Q80VPU408O) | CALCIUM FLUORIDE | 12 [hp_X] |
| TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28) (CALCIUM CATION - UNII:2M83C4R6ZB) | CALCIUM CATION | 12 [hp_X] |
| CHAMOMILE (UNII: FGL3685T2X) (CHAMOMILE - UNII:FGL3685T2X) | CHAMOMILE | 8 [hp_X] |
| FERROSO FERRIC PHOSPHATE (UNII: 91GQH8I5F7) (FERROSO FERRIC PHOSPHATE - UNII:91GQH8I5F7) | FERROSO FERRIC PHOSPHATE | 12 [hp_X] |
| PODOPHYLLUM (UNII: 2S713A4VP3) (PODOPHYLLUM - UNII:2S713A4VP3) | PODOPHYLLUM | 12 [hp_X] |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| CROSPROVIDONE, UNSPECIFIED (UNII: 2S7830E561) | |
| MANNITOL (UNII: 3OWL53L36A) | |
| SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | WHITE | Score | no score |
| Shape | ROUND | Size | 4mm |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:59262-502-26 | 1 in 1 BOX | 06/15/2018 | |
| 1 | | 135 in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| UNAPPROVED HOMEOPATHIC | | 06/15/2018 | |

Labeler - Similasan Corporation (111566530)