

ORALSOOTHE - calc fluor, calc phos, chamomilla, chamomilla, passiflora granule
Native Remedies, LLC

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.

OralSoothe

Relieves pain, crankiness & crying during teething

Active Ingredients: Each dose contains equal parts of: Calc fluor 8X HPUS, Calc phos 8X HPUS, Chamomilla 3X HPUS, Chamomilla 6C HPUS, Passiflora 3X HPUS.

Uses: Soothing homeopathic remedy for teething in babies and children.

Warnings: If symptoms persist or worsen, consult a healthcare professional.

If pregnant or breastfeeding, ask a health professional before use.

Keep this and all medication out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions: Babies: Sprinkle 1 pinch on the tongue when needed. Repeat after 20 minutes for up to 10 doses if needed.

Inactive Ingredients: Citric acid, corn starch, potassium sorbate, sucrose.

The letters HPUS indicate that the components in this products are officially monographed in the Homeopathic Pharmacopoeia of the United States.

All Native Remedies health products are specially formulated by experts in the field of natural health and are manufactured according to the highest pharmaceutical standards for maximum safety and effectiveness. For more information, visit us at www.nativeremedies.com

Distributed by

Native Remedies, LLC

6531 Park of Commerce Blvd.

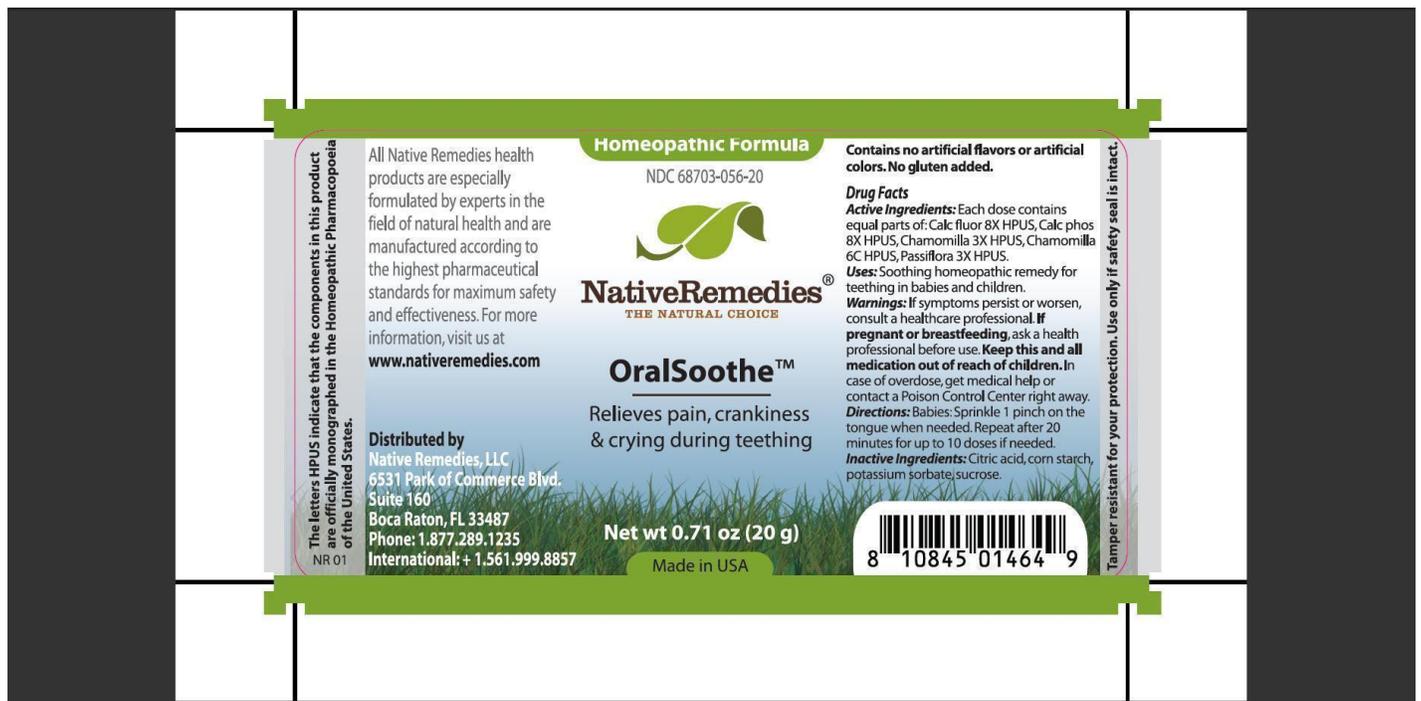
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Contains no artificial flavors or artificial colors. No gluten added.



ORALSOOTHE

calc fluor, calc phos, chamomilla, chamomilla, passiflora granule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68703-056
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALCIUM FLUORIDE (UNII: O3B55K4YK1) (FLUORIDE ION - UNII:Q80VPU408O)	CALCIUM FLUORIDE	8 [hp_X] in 16 mg
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28) (CALCIUM CATION - UNII:2M83C4R6ZB)	TRIBASIC CALCIUM PHOSPHATE	8 [hp_X] in 16 mg
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	3 [hp_X] in 16 mg
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	6 [hp_C] in 16 mg
PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS11O) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS11O)	PASSIFLORA INCARNATA FLOWERING TOP	3 [hp_X] in 16 mg

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
STARCH, CORN (UNII: O8232NY3SJ)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68703-056-20	20000 mg in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/08/2013	

Labeler - Native Remedies, LLC (192014186)**Establishment**

Name	Address	ID/FEI	Business Operations
King Bio		617901350	manufacture(68703-056) , api manufacture(68703-056)

Revised: 1/2013

Native Remedies, LLC