

GUNA-ORAL- achillea millefolium - aconitum napellus - arnica montana - atropa belladonna - calcium sulfide - comfrey root - echinacea angustifolia - echinacea purpurea - hypericum perforatum - sus scrofa tooth - witch hazel - spray
Guna spa

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.

GUNA-ORAL SPRAY

ACTIVE INGREDIENTS/PURPOSE

ACONITUM NAPELLUS 3X ANTI-INFLAMMATORY

ARNICA MONTANA 3X FEVER RELIEF

BELLADONNA 4X SWELLING

ECHINACEA ANGUSTIFOLIA 2X BACTERIAL INFECTION

ECHINACEA PURPUREA 2X IMMUNE SUPPORT

HAMAMELIS VIRGINIANA 2X SUPPORTS TISSUE REPAIR

HEPAR SULFURIS CALCAREUM 6X ANTIBACTERIAL IMMUNE SUPPORT

HYPERICUM PERFORATUM 3X PAIN RELIEF

MILLEFOLIUM 3X ORAL ANTI- INFLAMMATORY

SYMPHYTUM OFFICINALE 6X ORAL HYPERSENSITIVITY

TEETH 12X TOOTH HYPERSENSITIVITY

USES

Temporary relief of symptoms due to inflammation of the oral cavity such as:

- **Sore throat**
- **Inflamed gums**
- **Pharyngitis**

WARNINGS

- Stop use and ask doctor if symptoms persist more than 3 days.
- If pregnant or breast-feeding ask a health professional before use.
- Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.
- Contains ethyl alcohol 20%

PREGNANCY

If pregnant or breast-feeding ask a doctor before use

WARNINGS

Keep out of reach of children

DIRECTIONS

Adults and children 12 years and older 2 sprays, 3-5 times per day

Children between 12 years and 6 years of age 1 spray t, 3-5 times per day

Children under 6 years ask a doctor

QUESTIONS

Questions?: info@gunainc.com

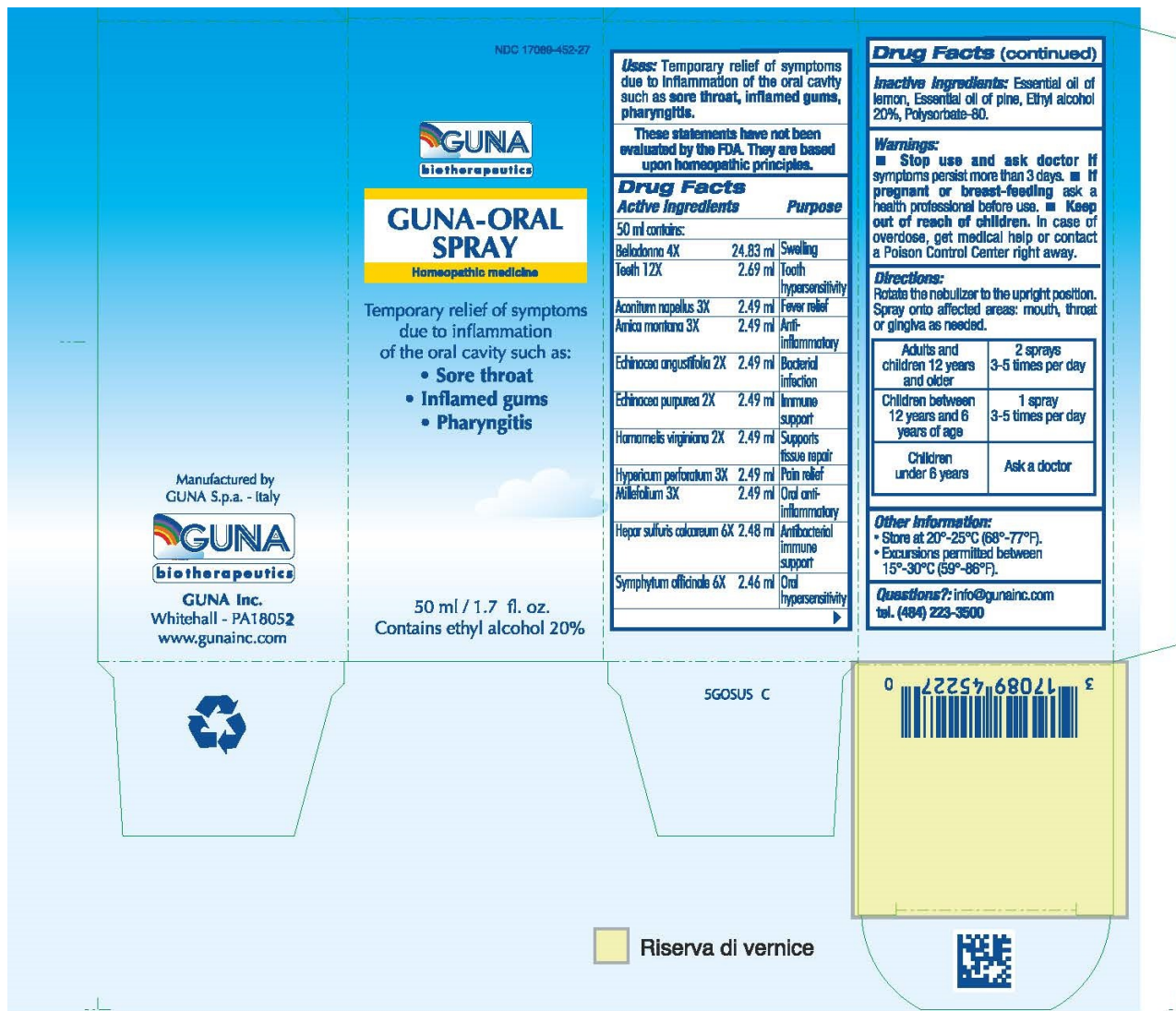
Tel. (484) 223-3500

Directions: Rotate the nebulizer to the upright position. Spray onto affected areas: mouth, throat or gingiva as needed.

Inactive ingredients: Essential oil of lemon, Essential oil of pine, Ethyl alcohol 20%, Polysorbate-80.

PRINCIPAL DISPLAY PANEL





GUNA-ORAL

achillea millefolium - aconitum napellus - arnica montana - atropa belladonna - calcium sulfide - comfrey root - echinacea angustifolia - echinacea purpurea - hypericum perforatum - sus scrofa tooth - witch hazel - spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17089-452
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	3 [hp_X] in 30 mL
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	3 [hp_X] in 30 mL
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	4 [hp_X] in 30 mL
ECHINACEA ANGUSTIFOLIA (UNII: VB06AV5US8) (ECHINACEA ANGUSTIFOLIA - UNII:VB06AV5US8)	ECHINACEA ANGUSTIFOLIA	2 [hp_X] in 30 mL

ECHINACEA PURPUREA (UNII: QI7G114Y98) (ECHINACEA PURPUREA - UNII:QI7G114Y98)	ECHINACEA PURPUREA	2 [hp_X] in 30 mL
WITCH HAZEL (UNII: 10 114J0 U34) (WITCH HAZEL - UNII:10 114J0 U34)	WITCH HAZEL	2 [hp_X] in 30 mL
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	6 [hp_X] in 30 mL
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	3 [hp_X] in 30 mL
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM - UNII:2FXJ6SW4PK)	ACHILLEA MILLEFOLIUM	3 [hp_X] in 30 mL
COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	6 [hp_X] in 30 mL
SUS SCROFA TOOTH (UNII: V69U5FL51F) (SUS SCROFA TOOTH - UNII:V69U5FL51F)	SUS SCROFA TOOTH	12 [hp_X] in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ABIES SACHALINENSIS VAR. SACHALINENSIS OIL (UNII: 9H7TY1ZV7Q)	
ALCOHOL (UNII: 3K9958V90M)	
LEMON OIL (UNII: I9GRO824LL)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17089-452-27	1 in 1 BOX	12/21/2018	
1		50 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		05/27/2010	

Labeler - Guna spa (430538264)

Establishment

Name	Address	ID/FEI	Business Operations
Guna spa		338587646	manufacture(17089-452)