

FLAVOBAC HEALTH GUARD COMPLETE- mouth spray against sore throat pain irritation spray
Oral Science Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Oral Science-ColdFlu Spray updated label

Active Ingredient(s)

Menthol 0.02%.....Anesthetic/Analgesic

Glycerin 10%.....Oral Demulcent

Purpose

Anesthetic/Analgesic

Oral Demulcent

Use

temporary relief of occasional minor irritation, pain, sore mouth, sore throat, minor discomfort and protection of irritated areas in sore mouth and sore throat

Warnings

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea or vomiting, consult a doctor promptly

Stop use and ask a doctor or dentist if sore mouth symptoms do not improve in 7 days
If pregnant or breast-feeding, ask a health professional before use

Keep out of the reach of children.

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

Do not exceed the recommended dosage. When using this product, try to avoid swallowing spray

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If pregnant or breast-feeding, ask a health professional before use

Do not exceed the recommended dosage.

sore mouth symptoms do not improve in 7 days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children 2 years of age and older: apply 4 sprays to the affected area. Gargle, swish around, or allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor

children under 12 years of age: should be supervised in the use of this product

children under 2 years of age: not recommended

Inactive ingredients

Purified Water, bioflavonoids, xylitol, polysorbate 20, disodium phosphate, ethanol, orange flavor, potassium sorbate, stevia, sodium hyaluronate, sucralose

Package Label - Principal Display Panel

New

**FLAVOBAC™
HEALTH
GUARD™
Complete**

**FLAVOBAC™
HEALTH
GUARD™
Complete**

**FLAVOBAC™
HEALTH
GUARD™
Complete**

**Spray in
the mouth**

**Allow to
remain for
1 minute**

Spit out

**Mouth Spray against
Sore Throat, Pain and
Irritation**

**Oral
Demulcent
2oz e**

Drug Facts

Active Ingredients	Purpose
Menthol 0.2%	Anesthetic/Analgesic
Glycerin 10%	Oral Demulcent

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RECOMMENDED BY HEALTH PROFESSIONALS

Questions?
1.888.442.7070
FlavobacHealth.com

Distributor:
Oral Science Inc.
9575-D Rue Ignace
Brossard, Q.C., J4V 2P3, CA
1.888.442.7070

Manufacturer:
Laboratoires MSP Inc.
2401 Montée de Picardie
Varennes, Q.C. J3X 0J1, CA

6 63635 00165 3

LOT

US-M-FH-VB08b6HG-20Z

59 mL NDC: 81359-121-11

FLAVOBAC HEALTH GUARD COMPLETE

mouth spray against sore throat pain irritation spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81359-121
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.02 mg in 100 mL
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	10 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SUCRALOSE (UNII: 96K6UQ3ZD4)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
XYLITOL (UNII: VCQ006KQ1E)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
STEVIA LEAF (UNII: 6TC6NN0876)	
ALCOHOL (UNII: 3K9958V90M)	
ORANGE (UNII: 5EVU04N5QU)	
CITRUS BIOFLAVONOIDS (UNII: BD70459I50)	
WATER (UNII: 059QF0KO0R)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81359-121-11	1 in 1 BOX	05/14/2021	
1		59 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/14/2021	

Labeler - Oral Science Inc (200633202)

Revised: 10/2022

Oral Science Inc