

**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.*

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**Oral Science-ColdFlu Spray**

**Active Ingredient(s)**

Menthol 0.04%.....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

try to avoid swallowing spray

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**

For 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 it out. Use up to 4 times daily or as directed by a dentist or doctor

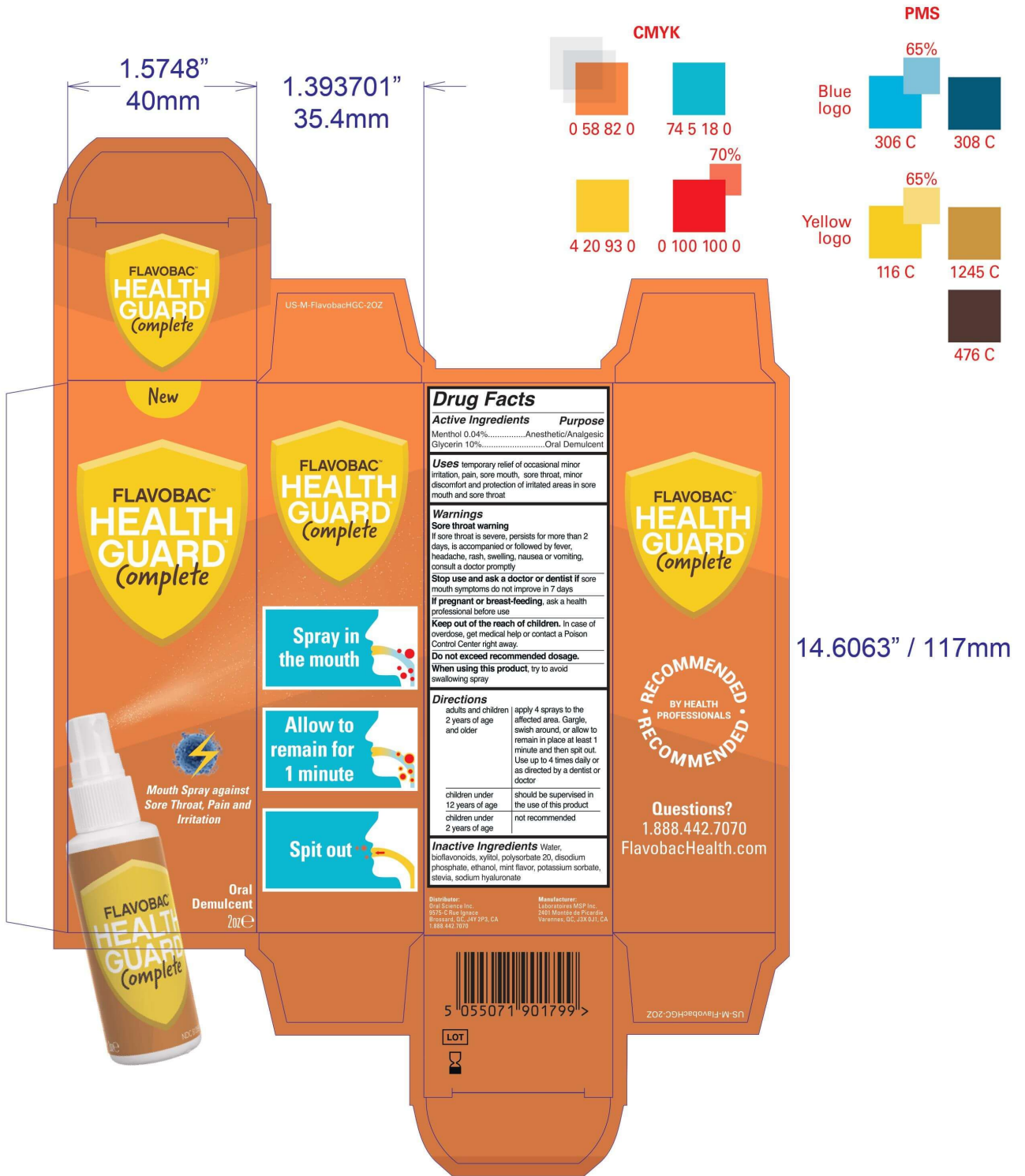
children under 12 years of age: should be supervised in the use of this product

children under 2 years of age: not recommended

### **Inactive ingredients**

purified Water, bioflavonoids, xylitol, polysorbate 20, disodium phosphate, ethanol, mint flavor, potassium sorbate, stevia, sodium hyaluronate

### **Package Label - Principal Display Panel**



59 mL NDC: 81359-111-11

## FLAVOBAC HEALTH GUARD COMPLETE

mouth spray against sore throat pain irritation spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81359-111
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.04 mg in 100 mL
<b>GLYCERIN</b> (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	10 mg in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>STEVIA LEAF</b> (UNII: 6TC6NN0876)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>MINT</b> (UNII: FV98Z8GITP)	
<b>CITRUS BIOFLAVONOIDS</b> (UNII: BD70459I50)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:81359-111-11	1 in 1 BOX	01/15/2021	
1		59 mL in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part356	01/15/2021	

**Labeler** - Oral Science Inc (200633202)

Revised: 10/2022

Oral Science Inc