

**KOFIX GINGER- menthol lozenge**  
**Global Health Solution LLC**

*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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**KOFIX® LOZENGES**

***Drug Facts***

***Active ingredient (in each lozenge)***

Menthol 9.3 mg

***Purpose***

Cough suppressant / Oral anesthetic

***Uses***

for the temporary relief of

- cough occurring with a cold
- occasional minor irritation, pain, sore mouth, and sore throat

***Warnings***

**Sore throat warning:** Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult physician promptly. Do not use more than 2 days or administer to children under 5 years of age unless directed by physician

**Ask a doctor before use if you have** persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus)

**When using this product** do not exceed recommended dosage

**Stop use and ask a doctor if**

- cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition
- sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting
- sore mouth symptoms do not improve in 7 days
- irritation, pain, or redness persists or worsens

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

**Keep this and all drugs out of the reach of children.**

### ***Directions***

- adults and children 5 years and over: dissolve one lozenge slowly in the mouth. Repeat every 2 hours as needed or as directed by a doctor
- children under 5 years of age: ask a doctor

### ***Other information***

- store at a cool and dry place 20°C - 25°C (68°F - 77°F) • protect from heat, humidity and direct sunlight

### ***Inactive ingredients***

caramel, clove oil, cornstarch, eucalyptus oil, ginger flavor, ginger oil, gum arabic, sugar

### ***Questions?***

**+1-800-550-4741, You may also report serious side effects to this phone number.** Monday to Friday, 9 AM - 6 PM EST.

**MENTHOL COUGH SUPPRESSANT/ORAL ANESTHETIC**

**SORE THROAT RELIEF**

**GINGER FLAVOR**

**8.6 calories per lozenge**

**MADE IN TURKEY**

### ***Distributed by:***

*Global Health Solution LLC,  
8328 Kings Ridge Court,  
Springfield, VA 22153*

### **Packaging**

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**KOFIX<sup>®</sup> LOZENGES** GINGER FLAVOR

MENTHOL COUGH SUPPRESSANT/ORAL ANESTHETIC

**KOFIX<sup>®</sup> LOZENGES**

**MENTHOL COUGH SUPPRESSANT/  
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**SORE THROAT RELIEF**

**24 Counts** GINGER FLAVOR

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**KOFIX<sup>®</sup> LOZENGES**

MENTHOL COUGH SUPPRESSANT/  
ORAL ANESTHETIC

**SORE THROAT RELIEF**

**4 Counts** GINGER FLAVOR

**KOFIX<sup>®</sup> LOZENGES**

MADE IN TURKEY

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**DRUG FACTS LABEL**

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**KOFIX GINGER**  
menthol lozenge

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:82340-001

<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	9.3 mg	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>	<b>Strength</b>		
	<b>CARAMEL</b> (UNII: T9D99G2B1R)			
	<b>CLOVE OIL</b> (UNII: 578389D6D0)			
	<b>STARCH, CORN</b> (UNII: O8232NY3SJ)			
	<b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662)			
	<b>GINGER OIL</b> (UNII: SAS9Z1SVUK)			
	<b>ACACIA</b> (UNII: 5C5403N26O)			
	<b>SUCROSE</b> (UNII: C151H8M554)			
<b>Product Characteristics</b>				
<b>Color</b>	brown	<b>Score</b>	no score	
<b>Shape</b>	ROUND	<b>Size</b>	19mm	
<b>Flavor</b>	GINGER	<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:82340-001-24	2 in 1 BOX	11/01/2021	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:82340-001-04	1 in 1 BOX	01/06/2022	
2		4 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph final	part341	11/01/2021		

**Labeler** - Global Health Solution LLC (117922627)

