#### SUGAR FREE HONEY-LEMON FISHERMANS FRIEND MENTHOL COUGH SUPPRESSANT- menthol lozenge Lofthouse of Fleetwood, Ltd.

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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**Honey Lemon** 

#### **Drug Facts**

Active ingredient (in each lozenge)

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Menthol 5.52 mg

#### **Purpose**

Cough suppressant/oral anesthetic.

#### Uses

temporarily relieves • occasional minor sore throat • cough due to minor throat and bronchial irritation occuring with the common cold or inhaled irritants

## <u>Warnings</u>

**Sore throat warning:** Severe or persistent sore throat or sore throat that occurs with high fever, headache, nausea, and vomiting may be serious. Ask a doctor right away. Do not use more than 2 days or give to children under 2 years of age unless directed by a doctor.

#### Ask Doctor

Ask a doctor before use if you have • a cough that occurs with too much phlegm (mucus) • a persistent or chronic cough that lasts such as occurs with smoking, asthma, or emphysema.

## When Using

When using this product do not use more than directed.

## Stop Use

Stop use and ask a doctor if • cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition. •

sore throat is severe, lasts more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting.

#### **Pregnant or Breast Feeding**

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

#### **Keep Out of Reach of Children**

Keep out of reach of children.

#### **Directions**

• adults and children 2 years of age and over: allow 1 lozenge to dissolve slowly in the mouth • repeat every 2 hours as needed or as directed by a doctor • children under 2 years of age: ask a doctor

#### **Inactive Ingredients**

**Inactive ingredients** acesulfame K, citric acid, honey lemon flavor, magnesium stearate, sorbitol, sucralose.

FISHERMAN'S FRIEND

HONEY-LEMON

Menthol Cough Suppressant/Oral Anesthetic

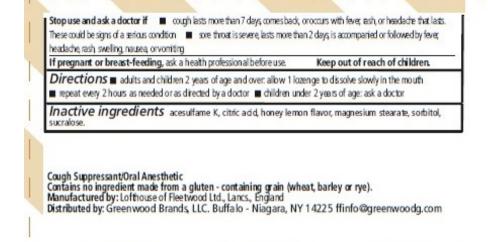
**SUGAR FREE** 

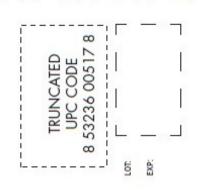
40 CT

Manufactured by: Lofthouse of Fleetwood Ltd., Lancs, England

Distributed by: Greenwood Brands, LLC, Buffalo-Niagra, NY 14225

ffinfo@greenwoodg.com









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# SUGAR FREE HONEY-LEMON FISHERMANS FRIEND MENTHOL COUGH SUPPRESSANT

menthol lozenge

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55711-071	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.52 mg		

Inactive Ingredients				
Ingredient Name	Strength			
MAGNESIUM STEARATE (UNII: 70097M6I30)				
SORBITOL (UNII: 506T60A25R)				
ACESULFAME (UNII: MA3UYZ6K1H)				
CITRIC ACID ACETATE (UNII: DSO12WL7AU)				
SUCRALOSE (UNII: 96K6UQ3Z D4)				

Product Characteristics				
Color	white (White lozenge with honey-colored spots)	Score	score with uneven pieces	
Shape	OVAL (Oval lozenge 22mm x 13mm)	Size	20mm	
Flavor	LEMON (Honey-Lemon Flavor)	<b>Imprint Code</b>		
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	01	2 in 1 PACKET; Type 0: Not a Combination Product	05/02/2019	
2	NDC:55711-071- 03	2 in 1 BAG	05/02/2019	
2		20 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:55711-071- 02	20 in 1 PACKET; Type 0: Not a Combination Product	05/02/2019	
4	NDC:55711-071- 04	2 in 1 BOX	05/02/2019	
4		20 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/02/2019	

## Labeler - Lofthouse of Fleetwood, Ltd. (212605588)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Lofthouse of Fleetwood, Ltd.		212605588	manufacture(55711-071)	