

**ORIGINAL EXTRA STRONG ALL NATURAL 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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**Original Extra Strong 20 Lozenges**

***Drug Facts***

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

Menthol 10 mg

***Purpose***

Cough suppressant/oral anesthetic

***Uses***

temporarily relieves

- occasional minor sore throat
- cough due to minor throat and bronchial irritation occurring with the common cold or inhaled irritants

***Warnings***

**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 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 this product**

do not use more than directed

**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

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

**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***

capsicum, dextrin, eucalyptus oil, natural licorice, sugar, tragacanth

FISHERMAN'S FRIEND®

ORIGINAL EXTRA STRONG

Menthol Cough Suppressant Lozenges

Cough Suppressant/Oral Anesthetic

20 Lozenges

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

Distributed by: Greenwood Brands, LLC. Buffalo-Niagara, NY 14225

ffinfo@greenwoodg.com

**Drug Facts**

**Active ingredient (in each lozenge)** Menthol 10 mg..... Cough suppressant/oral anesthetic.

**Purpose**

**Uses** temporarily relieves ■ occasional minor sore throat ■ cough due to minor throat and bronchial irritation occurring with the common cold or inhaled irritants

**Warnings**

**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 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 this product do not use more than directed.**

**Stop use and ask a doctor if** ■ cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. ■ sore throat is severe, lasts more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting

These could be signs of a serious condition



EST. 1865

# FISHERMAN'S FRIEND®

## ORIGINAL EXTRA STRONG

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Cough Suppressant/Oral Anesthetic  
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 Distributed by: Greenwood Brands, LLC. Buffalo-Niagara, NY 14225 ffinfo@greenwoodg.com

**20 LOZENGES**

TRUNCATED  
 UPC CODE  
 8 53236 00505 5

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**Inactive ingredients** capicum, dextrin, eucalyptus oil, natural licorice, sugar, tragacanth.

EXP  
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Keep out of reach of children. If pregnant or breast-feeding, ask a health professional before use.

# ORIGINAL EXTRA STRONG ALL NATURAL FISHERMANS FRIEND MENTHOL COUGH SUPPRESSANT

menthol lozenge

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55711-064
Route of Administration	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg

**Inactive Ingredients**

Ingredient Name	Strength
CAPSICUM (UNII: 00UK7646FG)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
LICORICE (UNII: 61ZBX54883)	
RAW SUGAR (UNII: 8M707QY5GH)	
TRAGACANTH (UNII: 2944357O2O)	

**Product Characteristics**

Color	brown (light brown)	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55711-064-01	20 in 1 PACKET; Type 0: Not a Combination Product	08/10/2010	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/10/2010	

**Labeler** - Lofthouse of Fleetwood, Ltd. (212605588)**Establishment**

Name	Address	ID/FEI	Business Operations
Lofthouse of Fleetwood, Ltd.		212605588	manufacture(55711-064)