

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.

Drug Facts

Active ingredient (in each lozenge)

Menthol 10 mg

Purpose

Cough suppressant/oral anesthetic

Uses

temporarily relieves

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

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.

Keep out of reach of children.

Ask a doctor before use if you have

- 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

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

Principal Display Panel

Original Extra Strong

All Natural

Since Lofthouse's 1865

Fisherman's Friend

Menthol Cough Suppressant Lozenges

Cough Suppressant/Oral Anesthetic

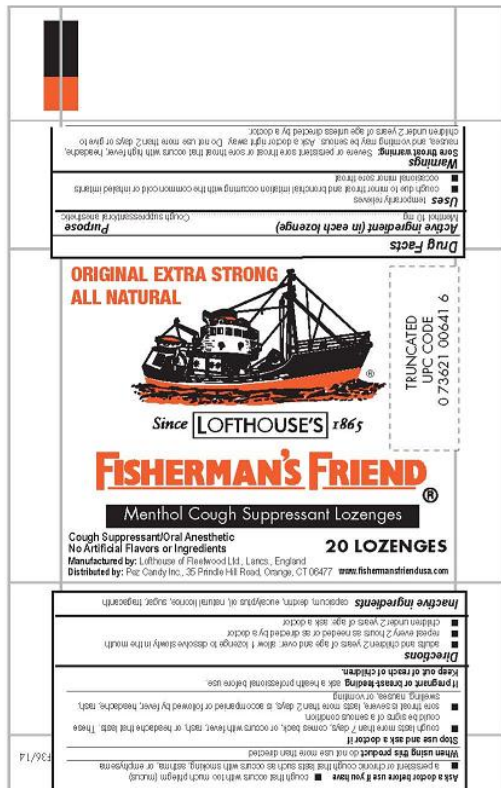
No Artificial Flavors or Ingredients

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

Distributed by: Pez Candy Inc., 35 Prindle Hill Road, Orange, CT 06477

www.fishermansfriendusa.com

20 Lozenges



Enlarged text for copy checking

Drug Facts	
Active ingredient (in each lozenge) Menthol 10 mg	Purpose Cough suppressant/oral anesthetic
Uses temporarily relieves <ul style="list-style-type: none"> cough due to minor throat and bronchial irritation occurring with the common cold or inhaled irritants occasional minor sore throat 	
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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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	

F36/14 - U.S.A. RED 20 COUNT (25g) FOIL

Approved by: _____

Date: 3rd May 2007

For exact size and buying standard please refer to Lofthouse Packaging Manual.
Section 4 Reference S4/001

N.B. "Since 1865" in Sabon Antiqua typeface,
product description flash prints BLACK
UPC CODE IS TRUNCATED

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)

