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.

064-05

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

Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor. If sore throat is severe or persists more than 2 days accompanied by headache, nausea, and vomiting, contact a doctor right away. If sore mouth symptoms do not improve in 7 days, see your dentist of doctor promptly.

Keep out of reach of children.

When using this product do not use more than directed

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

Directions

- adults and children 2 to under 12 years of age: allow lozenge to dissolve slowly in the mouth
- may be repeated every hour as needed for cough, or every 2 hours as needed for sore throat, or as directed by a doctor
- children under 2 years of age: consult a doctor

Inactive ingredients

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

Principal Display Panel

Original

Extra

Strong

Trial Size

Since Lofthouse's 1865

Fisherman's Friend

Menthol Cough Suppressant Lozenges

Cough Suppressant/Oral Anesthetic

No Artificial Flavors or Ingredients

2 Lozenges

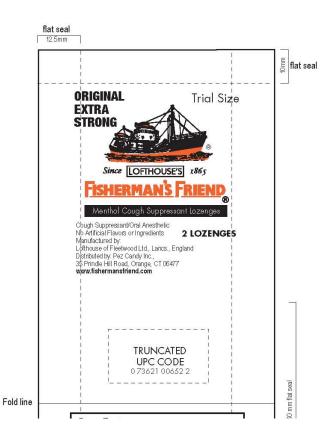
Manufactured by:

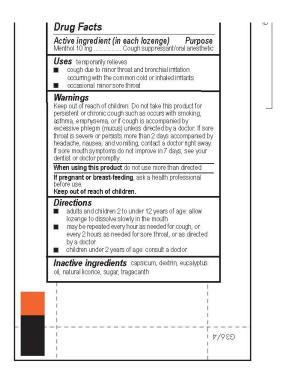
Lofthouse of Fleetwood Ltd., Lancs., England

Distributed by: Pez Candy Inc.

35 Prindle Hill Road, Orange, CT 06477

www.fishermansfriend.com





G36/4 - U.S.A. RED 2 COUNT SAMPLE FOIL

Approved by: _____

Date: 25th February 2004

For exact size and buying standard please refer to Lofthouse Packaging Manual Section 7 Reference S7/020

NB "Since 1865" in Sabon Antiqua typeface, product description 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 ma			

Inactive Ingredients			
Ingredient Name	Strength		
CAPSICUM (UNII: 00UK7646FG)			

EUCALYPTUS OIL (UNII: 2R04ONI662)	
LICORICE (UNII: 61ZBX54883)	
RAW SUGAR (UNII: 8M707QY5GH)	
TRAGACANTH (UNII: 2944357020)	

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	
	2 in 1 PACKET; Type 0: Not a Combination Product	09/08/2010		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/08/2010	

Labeler - Lofthouse of Fleetwood, Ltd. (212605588)

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

Revised: 6/2021 Lofthouse of Fleetwood, Ltd.