

**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

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 or 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

Fisherman's Friend

Menthol Cough Suppressant Lozenges

Original

Extra

Strong

Distributed by: Pez Candy Inc.,

35 Prindle Hill Road,

Orange, CT 06477

Made in England

35 Lozenges

FISHERMAN'S FRIEND ORIGINAL
Menthol Cough Suppressant Lozenges EXTRA
STRONG

Distributed by: Pez Candy Inc.,
35 Prindle Hill Road,
Orange, CT 06477
Made in England
35 LOZENGES
LOT 060666 EXP 05 09

TRUNCATED
UPC CODE
0 73621 00649 2

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P36/5

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P36/5

Label prints black on white.

Fonts:

ArialNarrow, regular, bold, bold italic

P36/5 USA RED 40G (35 COUNT) TIN LABEL
Label prints black on white.

Approved by: _____

Date: 16th June 2006-

For exact size and buying standard refer to Lofthouse Packaging Manual
Section 10, Reference S10/002

**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: 294435702O)	

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:55711-064-06	35 in 1 BOX; 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)

Revised: 12/2018

Lofthouse of Fleetwood, Ltd.