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.

Original Extra Strong 2 bags of 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, sweling, 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

Principal Display Panel

FISHERMAN'S FRIEND

ORIGINAL EXTRA STRONG

Menthol Cough Suppressant Lozenges

2 Bags of 20 Lozenges

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

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

ffinfo@greenwoodg.com

Stopuse and ask a doctor if 🔳 cough lats more than 7 day, comes bad; procours with leve; eigh or headachethal 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 rath, swelling, nausea or vomiting

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ORIGINAL EXTRA STRONG ALL NATURAL FISHERMANS FRIEND **MENTHOL COUGH SUPPRESSANT**

menthol lozenge

Product Information				
Prod	uct Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55711-064
Rout	e of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients				
Ingredient Name	Strength			
CAPSICUM (UNII: 00UK7646FG)				
EUCALYPTUS OIL (UNII: 2R040NI662)				
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				

P	Packaging					
#	tem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:55711-064- 03	2 in 1 PACKAGE	08/10/2010			
1		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	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: 5/2021 Lofthouse of Fleetwood, Ltd.