MGC HEALTH- cough drops black cherry sugar free lozenge YUNNAN BAIYAO GROUP CO., 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.

YNBY-MGC BC SF 25-70 2023

Active Ingredient(s)

Menthol 5.8

Purpose

Purposes cough suppressant, oral anesthetic

Use

temporary relieves: ■ cough due to cold ■ occasional minor irritation or sore throat

Warnings

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or follow headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. These may be serious.

Ask a doctor before use if you have: \blacksquare persistent or chronic cough such as occurs with smoking, asthma, or emphysema \blacksquare cough accompanied by excessive phlegm (mucus).

Stop use and ask a doctor if ■ cough persists for more than 1 week, tends to recur, or is accompained by fever, rash, or persistent headache. These could be signs of a serius condition. ■ sore mouth does not improve in 7 days ■ irritation, pain, or redness persists or worsens.

Keep out of reach of children.

Directions

- adults and children 5 years and over: dissolve 1 drop slowly in the mouth. Repeat every 2 hours as needed.
- children under 5 years: ask a doctor.

Other information

phenylketonurics: contains phenylalanine 2 mg per drop excessive consumption may have a laxative effect

contains: SOY.

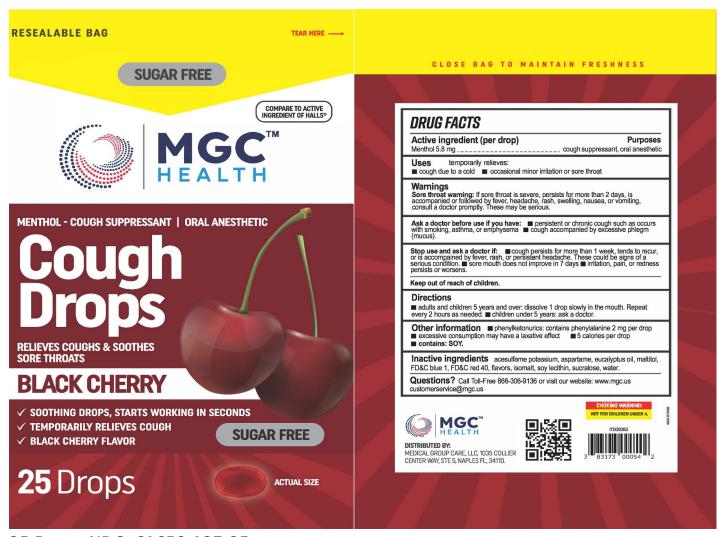
-5 calories per drop

Inactive ingredients

Acesulfame potassium, aspartame, eucalyptus oil, maltitol, FD&C blue 1. FD&C red 40, flavors. isomalt, soy lecithin, sucralose, water.

Call Toll-Free 866-306-9136 or visit our website: www.mgc.us customerservice@mgc.us

Package Label - Principal Display Panel



25 Drops NDC: 61658-127-25

MGC HEALTH cough drops black cherry sugar free lozenge Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:61658-127

Active Ingredient/Active Moiety
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Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.8 ma

Inactive Ingredients			
Ingredient Name	Strength		
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)			
EUCALYPTUS OIL (UNII: 2R040NI662)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
ISOMALT (UNII: S870P55O2W)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)			
WATER (UNII: 059QF0KO0R)			
ASPARTAME (UNII: Z0H242BBR1)			

Product Characteristics			
Color	red	Score	score with uneven pieces
Shape	OVAL	Size	21mm
Flavor	MENTHOL	Imprint Code	В
Contains			

II	Packaging						
	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
	1 NDC:61658-127- 25	25 in 1 BAG; Type 0: Not a Combination Product	09/01/2023				
	2 NDC:61658-127-	70 in 1 BAG; Type 0: Not a Combination Product	09/01/2023				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	09/01/2023		

Labeler - YUNNAN BAIYAO GROUP CO., LTD (654223122)

Registrant - Medical Group Care LLC (085137089)