

HALLS CHERRY- menthol lozenge
Mondelez Global LLC

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.

HALLS CHERRY bag

Active Ingredient

<(per drop) Menthol 5.8 mg>

Purposes

<Cough Suppressant, Oral Anesthetic>

Uses

<temporarily relieves:>

- cough due to a cold
- occasional minor irritation or sore throat

Warnings

<Sore throat warning: if sore throat is severe, persists for more than 2 days, is accompanied by fever, headache, rash, swelling, or vomiting, consult a doctor promptly. These may be serious.>

Ask a doctor before use if you have

- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- 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 accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.
- sore mouth does not improve in 7 days
- irritation, pain, or redness persists or worsens

Keep out of reach of children

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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

- 10 calories per drop
- Contains: SOY

Inactive ingredients

<eucalyptus oil, FDC blue 2, FDC red 40, flavors, glucose syrup, soy lecithin, sucralose, sucrose, water>

Questions

<Call **1-800-524-2854**, Monday to Friday, 9AM-6PM Eastern Time or **visit our website at www.gethalls.com**>

OTC Principal Display Panel



HALLS CHERRY

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12546-109
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.8 mg

Inactive Ingredients

Ingredient Name	Strength
EUCALYPTUS OIL (UNII: 2R04ONI662)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KOOR)	

Product Characteristics

Color	red (RED)	Score	no score
Shape	OVAL	Size	21mm
Flavor	CHERRY (CHERRY)	Imprint Code	H
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-109-18	18 in 1 BAG; Type 0: Not a Combination Product	03/31/2019	09/19/2022
2	NDC:12546-109-30	30 in 1 BAG; Type 0: Not a Combination Product	03/31/2019	
3	NDC:12546-109-24	24 in 1 BAG; Type 0: Not a Combination Product	12/02/2019	06/11/2023
4	NDC:12546-109-40	40 in 1 BAG; Type 0: Not a Combination Product	03/31/2019	08/21/2023
5	NDC:12546-109-80	80 in 1 BAG; Type 0: Not a Combination Product	03/31/2019	
6	NDC:12546-109-89	200 in 1 BAG; Type 0: Not a Combination Product	03/31/2019	
7	NDC:12546-109-16	16 in 1 BAG; Type 0: Not a Combination Product	03/31/2019	12/31/2020
8	NDC:12546-109-96	96 in 1 BAG; Type 0: Not a Combination Product	03/31/2019	04/21/2020
9	NDC:12546-109-14	14 in 1 BAG; Type 0: Not a Combination Product	03/31/2019	
10	NDC:12546-109-99	160 in 1 PACKAGE; Type 0: Not a Combination Product	03/31/2019	
11	NDC:12546-109-01	100000 in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	12/02/2019	09/16/2022
12	NDC:12546-109-02	150000 in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	12/02/2019	09/16/2022
13	NDC:12546-109-03	2400 in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	12/02/2019	09/16/2022
14	NDC:12546-109-04	720 in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	12/02/2019	09/16/2022
15	NDC:12546-109-00	140 in 1 BAG; Type 0: Not a Combination Product	04/10/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/31/2019	

Labeler - Mondelez Global LLC (050964956)

Establishment

Name	Address	ID/FEI	Business Operations
Mondelez Canada Inc.		246791201	manufacture(12546-109)

Revised: 7/2023

Mondelez Global LLC