

**HALLS SUGAR FREE BLACK 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.*

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**Halls sugar free black 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, persist for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, 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**

- phenylketonurics: contains phenylalanine 2 mg per drop
- excessive consumption may have a laxative effect
- 5 calories per drop
- contains soy

**Inactive ingredients**

<acesulfame potassium, aspartame, eucalyptus oil, FDC blue 1, FDC red 40, flavors, isomalt, sodium carboxymethylcellulose, soy lecithin, water>

**Questions**

<Call 1-800-524-2854, Monday to Friday, 9 AM-6PM Eastern Time or visit our website at [www.gethalls.com](http://www.gethalls.com)>

**OTC Principal Display Panel**



**HALLS SUGAR FREE BLACK CHERRY**  
menthol lozenge

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12546-104
Route of Administration	ORAL		

<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	5.8 mg	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>		<b>Strength</b>		
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)				
ASPARTAME (UNII: Z0H242BBR1)				
EUCALYPTUS OIL (UNII: 2R04ONI662)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
ISOMALT (UNII: S870P55O2W)				
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)				
WATER (UNII: 059QF0KO0R)				
<b>Product Characteristics</b>				
<b>Color</b>	red (dark red)	<b>Score</b>	no score	
<b>Shape</b>	OVAL	<b>Size</b>	21mm	
<b>Flavor</b>	CHERRY (Black Cherry)	<b>Imprint Code</b>	H	
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12546-104-25	25 in 1 BAG; Type 0: Not a Combination Product	06/10/2019	
2	NDC:12546-104-30	30 in 1 BAG; Type 0: Not a Combination Product	06/10/2019	06/21/2022
3	NDC:12546-104-70	70 in 1 BAG; Type 0: Not a Combination Product	06/10/2019	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	06/10/2019		

**Labeler** - Mondelez Global LLC (050964956)

### Establishment

Name	Address	ID/FEI	Business Operations
Mondelez Canada Inc		246791201	manufacture(12546-104)