

COUGH DROPS- menthol granule
Xiamen Kang Zhongyuan Biotechnology 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.

Active Ingredient

Menthol 0.18%

Purpose

cough suppressant,oral anesthetic

Use

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.

Do not use

persistent or chronic cough such as occurs cough accompanied by excessive phlegm with smoking, asthma, or emphysema (mucus).

Stop Use

Stop use and ask a doctor if:

1,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.

2, sore mouth does not improve in 7 days

3,irritation, pain, or redness persists or worsens.

Keep Out Of Reach Of Children

Please do not place this product in an area accessible to unconscious people.

In case of accidental ingestion, seek medical help right away.

Directions

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

Other information

1,10 calories per drop

2, contains soy

Inactive ingredients

citric acid, eucalyptus oil, FD&C blue 1, FD&C red 40, flavors, glucose syrup, potassium citrate, soy lecithin, sucralose, sucrose, water.

Questions

Call 2396311907 or visit our website : www.mgc.us

PRINCIPAL DISPLAY PANEL

RESEALABLE BAG 5 6 30 9 **TEAR HERE**

COMPARE TO ACTIVE INGREDIENT OF HALLS[®]

MGC HEALTH

MENTHOL - COUGH SUPPRESSANT | ORAL ANESTHETIC

10

Cough Drops

RELIEVES COUGHS & SOOTHES SORE THROATS

HONEY LEMON

- ✓ SOOTHING DROPS, STARTS WORKING IN SECONDS
- ✓ TEMPORARILY RELIEVES COUGH
- ✓ HONEY LEMON FLAVOR

30 Drops ACTUAL SIZE

DRUG FACTS

Active ingredient (per drop)	Purposes
Menthol 7.5 mg	cough suppressant, oral anesthetic

Uses temporarily 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 followed by 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 throat 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 ■ 10 calories per drop ■ contains: SOY.

Inactive ingredients beta carotene, eucalyptus oil, flavors, glucose syrup, honey, soy lecithin, sucralose, sucrose, water.

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CHOKING WARNING
NOT FOR CHILDREN UNDER 4

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SUGAR FREE COMPARE TO ACTIVE INGREDIENT OF HALLS[®]

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MENTHOL - COUGH SUPPRESSANT | ORAL ANESTHETIC

Cough Drops

RELIEVES COUGHS & SOOTHES SORE THROATS

HONEY LEMON



- ✓ SOOTHING DROPS, STARTS WORKING IN SECONDS
- ✓ TEMPORARILY RELIEVES COUGH
- ✓ HONEY LEMON FLAVOR

SUGAR FREE

70 Drops  ACTUAL SIZE

CLOSE BAG TO MAINTAIN FRESHNESS

DRUG FACTS

Active ingredient (per drop)	Purposes
Menthol 7.6 mg	cough suppressant, oral anesthetic

Uses temporarily 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: ■ 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.

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 ■ 5 calories per drop ■ contains: SOY.

Inactive ingredients beta carotene, eucalyptus oil, flavors, isomalt, soy lecithin, sucralose, maltitol, water.

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WARNING
 NOT FOR CHILDREN UNDER 4

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 **MGC HEALTH**

MENTHOL - COUGH SUPPRESSANT | ORAL ANESTHETIC

Cough Drops

RELIEVES COUGHS & SOOTHES SORE THROATS

MENTHOL



CLOSE BAG TO MAINTAIN FRESHNESS

DRUG FACTS

Active ingredient (per drop)	Purposes
Menthol 5.4 mg	cough suppressant, oral anesthetic

Uses temporarily 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: ■ 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.

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 citric acid, eucalyptus oil, FD&C blue 1, FD&C red 40, flavors, glucose syrup, potassium citrate, soy lecithin, sucralose, sucrose, water.

Questions? Call 2396311907 or visit our website: www.mgc-us.com



✓ SOOTHING DROPS, STARTS WORKING IN SECONDS
 ✓ TEMPORARILY RELIEVES COUGH
 ✓ MENTHOL FLAVOR

30 Drops  ACTUAL SIZE

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NET FOR CHILDREN UNDER 4

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COMPARE TO ACTIVE INGREDIENT OF HALLS®

MGC HEALTH

MENTHOL - COUGH SUPPRESSANT | ORAL ANESTHETIC

Cough Drops

RELIEVES COUGHS & SOOTHES SORE THROATS

MENTHOL

✓ SOOTHING DROPS, STARTS WORKING IN SECONDS
 ✓ TEMPORARILY RELIEVES COUGH
 ✓ MENTHOL FLAVOR

25 Drops  ACTUAL SIZE

DRUG FACTS

Active ingredient (per drop) Menthol 5.4 mg	Purposes cough suppressant, oral anesthetic
Uses temporarily relieves: <input type="checkbox"/> cough due to cold <input type="checkbox"/> 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: <input type="checkbox"/> persistent or chronic cough such as occurs with smoking, asthma, or emphysema <input type="checkbox"/> cough accompanied by excessive phlegm (mucus).	
Stop use and ask a doctor if: <input type="checkbox"/> 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. <input type="checkbox"/> sore mouth does not improve in 7 days <input type="checkbox"/> irritation, pain, or redness persists or worsens.	
Keep out of reach of children.	
Directions <input type="checkbox"/> adults and children 5 years and over: dissolve 1 drop slowly in the mouth. Repeat every 2 hours as needed. <input type="checkbox"/> children under 5 years: ask a doctor.	
Other information <input type="checkbox"/> 5 calories per drop <input type="checkbox"/> contains: SOY.	
Inactive ingredients acesulfame potassium, aspartame, sucralose, citric acid, eucalyptus oil, FD&C blue 1, FD&C red 40, flavors, isomalt, maltitol, potassium citrate, soy lecithin, water.	
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NET FOR CHILDREN UNDER 4

CLOSE BAG TO MAINTAIN FRESHNESS

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SUGAR FREE

COMPARE TO ACTIVE INGREDIENT OF HALLS®

MGC HEALTH

MENTHOL - COUGH SUPPRESSANT | ORAL ANESTHETIC

Cough

✓ SOOTHING DROPS, STARTS WORKING IN SECONDS
 ✓ TEMPORARILY RELIEVES COUGH
 ✓ MENTHOL FLAVOR

DRUG FACTS

Active ingredient (per drop) Menthol 5.8 mg	Purposes cough suppressant, oral anesthetic
Uses temporarily relieves: <input type="checkbox"/> cough due to cold <input type="checkbox"/> 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: <input type="checkbox"/> persistent or chronic cough such as occurs with smoking, asthma, or emphysema <input type="checkbox"/> cough accompanied by excessive phlegm (mucus).	

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NET FOR CHILDREN UNDER 4

CLOSE BAG TO MAINTAIN FRESHNESS

Cough Drops

RELIEVES COUGHS & SOOTHES SORE THROATS

CHERRY

- ✓ SOOTHING DROPS, STARTS WORKING IN SECONDS
- ✓ TEMPORARILY RELIEVES COUGH
- ✓ CHERRY FLAVOR

30 Drops
ACTUAL SIZE

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.

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, FD&C blue 2, FD&C red 40, flavors, glucose syrup, soy lecithin, sucralose, sucrose, water

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CHECKING WARNING:
NET FOR CHILDREN UNDER 6.

83173 00002

RESEALABLE BAG

TEAR HERE →

VALUE SIZE

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COMPARE TO ACTIVE INGREDIENT OF HALLS®

MENTHOL - COUGH SUPPRESSANT | ORAL ANESTHETIC

Cough Drops

RELIEVES COUGHS & SOOTHES SORE THROATS

MENTHOL

- ✓ SOOTHING DROPS, STARTS WORKING IN SECONDS
- ✓ TEMPORARILY RELIEVES COUGH
- ✓ MENTHOL FLAVOR

80 Drops
ACTUAL SIZE

CLOSE BAG TO MAINTAIN FRESHNESS

DRUG FACTS

Active ingredient (per drop)	Purposes
Menthol 5.4 mg	cough suppressant, oral anesthetic

Uses 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 followed by 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.

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 citric acid, eucalyptus oil, FD&C blue 1, FD&C red 40, flavors, glucose syrup, potassium citrate, soy lecithin, sucralose, sucrose, water.

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CHECKING WARNING:
NET FOR CHILDREN UNDER 6.
MENTHOL GRANULES 80

83173 00005

COUGH DROPS

menthol granule

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:83698-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.18 g in 100

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CORN SYRUP (UNII: 9G5L16BK6N)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83698-001-01	25 in 1 BOTTLE; Type 0: Not a Combination Product	09/13/2023	
2	NDC:83698-001-02	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/13/2023	
3	NDC:83698-001-03	70 in 1 BOTTLE; Type 0: Not a Combination Product	09/13/2023	
4	NDC:83698-001-04	80 in 1 BOTTLE; Type 0: Not a Combination Product	09/13/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/13/2023	

Labeler - Xiamen Kang Zhongyuan Biotechnology Co., Ltd. (411759931)

Establishment

Name	Address	ID/FEI	Business Operations
Xiamen Kang Zhongyuan Biotechnology Co., Ltd.		411759931	label(83698-001) , manufacture(83698-001)