MENTHOL COUGH DROPS- menthol pastille
LA TIA TRINI SA DE CV

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.

Menthol Cough Drops

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Menthol 5 mg Purpose: Cough suppressant.

Purpose

Cough suppressant

Uses

Temporarily relieves:
- Cough as may occur with a cold or inhaled irritants.
- Ocasional minor irritation and sore throat.

Warnings

Sore throat warning if sore throat is severe, persists, for more than 2 days, is accompained or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. This symptoms may be serious.

Ask a doctor before use if you have:

• Persistent or chronic cough such as occurs with smoking, asthma, or emphysema. • Cough accompained by excessive phlegm (mocus).

When using this product

Do not exceed recommended dosage.

Keep out of reach of children

Stop use and ask a doctor if

Cough persists for more than 7 days, tends to recur, or is accompained by fever, rash, or persisstent headache. This could be signs of a serious condition.

Sore throat is severe, or irritation, pain or redness lasts or worsens.

If pregmant or breast-feeding Ask a health professional before use.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 6 years and older: Disolve 1 drop slowly in the mouth. May be repeated every hour as needed.
- Children under 6 years: Use only under adult supervision.

Other information

Contains: Soy

Inactive Ingredients

Anhydrous dextrose, citric acid monohydrate, cordia boissieri whole, eucalyptus globulus leaf, FD&C Blue No.1, honey, mint, myrrh, propolis wax, sambucus nigra flower, soy lecithin, sucrose, verbascum densiflorum flower. Contains FD&C Yellow No. 5 (tartrazine) as a color additive.

Package Label - Menthol Drops

MentholDrops NDC: 72432-200-01

MENTHOL COUGH DROPS

menthol pastille

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72432-200
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.005 g in 4 g

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK)	
SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T)	
MYRRH (UNII: JC71GJ1F3L)	
MINT (UNII: FV98Z8GITP)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
HONEY (UNII: Y9H1V576FH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
VERBASCUM DENSIFLORUM FLOWER (UNII: N7FC535Q3R)	
CORDIA BOISSIERI WHOLE (UNII: 57NZE56C0Z)	
SUCROSE (UNII: C151H8M554)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics

Color	green	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor	LIME	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72432-200-01	36 g in 1 BLISTER PACK; Type 0: Not a Combination Product	07/13/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/13/2021	

Labeler - LA TIA TRINI SA DE CV (814376497)

Registrant - LA TIA TRINI SA DE CV (814376497)

Establishment

Name	Address	ID/FEI	Business Operations
LA TIA TRINI SA DE CV		814376497	manufacture(72432-200)