

LIBERA TOS - dextromethorphan hbr, guaifenesin liquid
RockHealth, Inc

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.

Libera Tos Children

Active Ingredients: (in each teaspoonful 5 ml.)	Purpose
Dextromethorphan Hydrobromide 5 mg	Cough Suppressant
Guaifenesin 75 mg	Expectorant

Uses:

- Temporarily relieves cough due to the common cold or inhaled irritants.
- Helps loosen mucus and bronchial secretions to make cough more productive.

Warnings

Do not use if taking a prescription Monoamine Oxidase Inhibitor(MAOI) (certain drugs for Depression, psychiatric, or emotional condition or parkinson’s disease), or for 2 weeks after stopping the MAOI Drug. If taking a prescription and do not know if it contains MAOI ask the Doctor before taking this product. Ask a Health Professional before use if: pregnant or breast feeding or suffer Diabetes. Stop use and ask a Doctor: if cough persists more than seven days or if accompanied by fever, rash, or persistent headache, these could be signs of a serious condition or illness.

Keep out of the reach of children, in case of accidental overdose seek professional assistance or contact a Poison Control Center immediately

Keep out of reach of children.

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

Directions

Shake well immediately before each use.
Do not exceed 6 doses in any 24 hour period.

AGE	DOSES
Children 6 to under 12 years of age	5 ml (1 tsp) every 4 hours
Children under 6 years of age	Do not use

Other Information:Do not use if seal or cap is broken or torn, measure cup is provided
Store at 20 - 25 °C (68 - 77 °F).

Inactive Ingredients:Aloe Vera, Caramel Color, Citric Acid, Eucalyptus, Pure Honey, Ginger,Honey flavor, Hydroxyethyl cellulose Pharm 250, Menthol, Methylparaben,Potassium Sorbate,Propylene Glycol, Propylparaben, Purified water,Sodium Chloride, Sucralose.

Questions or Comments?

please call: 305-791-8763

Manufactured by

Gadal Laboratories, Inc., Miami, FL 33186

Exclusively Distributed by

ROCKHEALTH, INC., Miami, FL 33018

Made in U.S.A.

LIBERA TOS			
dextromethorphan hbr, guaifenesin liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60840-0300
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)		DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)		GUAIFENESIN	75 mg in 5 mL
Inactive Ingredients			
Ingredient Name			Strength
ALOE (UNII: V5VD430YW9)			
CAMEL (UNII: T9D99G2B1R)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
EUCALYPTUS OIL (UNII: 2R04ONI662)			
HONEY (UNII: Y9H1V576FH)			
GINGER (UNII: C5529G5JPQ)			
HYDROXYETHYL CELLULOSE (140 MPAS AT 5%) (UNII: 8136Y38GY5)			
MENTHOL (UNII: L7T10EIP3A)			

METHYLPARABEN (UNII: A2I8C7H9T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60840-0300-1	118 mL in 1 BOTTLE		
2	NDC:60840-0300-2	178 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/01/2013	

Labeler - RockHealth, Inc (079130011)

Registrant - RockHealth, Inc (079130011)

Establishment

Name	Address	ID/FEI	Business Operations
RockHealth, Inc		079130011	LABEL(60840-0300)

Establishment

Name	Address	ID/FEI	Business Operations
Gadal Laboratories Inc		841305639	MANUFACTURE(60840-0300)

Revised: 11/2013

RockHealth, Inc