

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 Adult

Active Ingredients: (in each teaspoonful 5 ml.)	Purpose
Dextromethorphan Hydrobromide 10 mg	Cough Suppressant
Guaifenesin 100 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
Adults and Children 12 years and over	10 ml (2 tsps) every 4 hours
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.

Drug Facts	Drug Facts (continued)	Información General	Información General (continuación)																
Active Ingredients: (in each 5 mL, 1 teaspoon) Purpose: Dextromethorphan HBr - 10 mg - Cough Suppressant Guaifenesin - 100 mg - Expectorant	Directions: -Shake before each use. -Do not take more than 6 doses in a 24-hour period. <table border="1"> <thead> <tr> <th>Age</th> <th>Dose</th> </tr> </thead> <tbody> <tr> <td>Adults and children 12 years and over</td> <td>10 mL (2 tsp) every 4 hours</td> </tr> <tr> <td>Children 6 to under 12 years of age</td> <td>5 mL (1 tsp) every 4 hours</td> </tr> <tr> <td>Children under 6 years of age</td> <td>Do not use</td> </tr> </tbody> </table>	Age	Dose	Adults and children 12 years and over	10 mL (2 tsp) every 4 hours	Children 6 to under 12 years of age	5 mL (1 tsp) every 4 hours	Children under 6 years of age	Do not use	Ingredientes Activos: (en cada 5 mL, 1 cucharada) Propósito: Dextrometorfano HBr - 10 mg - Antitusivo Guafenesina - 100 mg - Expectorante	Instrucciones: -Agitar antes de cada uso. No tome más de 6 dosis en un período de 24 horas. <table border="1"> <thead> <tr> <th>Edad</th> <th>Dosis</th> </tr> </thead> <tbody> <tr> <td>Adultos y niños de 12 años y más</td> <td>10 mL (2 cucharaditas) cada 4 horas</td> </tr> <tr> <td>Niños de 6 a 12 años de edad</td> <td>5 mL (1 cucharadita) cada 4 horas</td> </tr> <tr> <td>Niños menores de 6 años</td> <td>No lo use</td> </tr> </tbody> </table>	Edad	Dosis	Adultos y niños de 12 años y más	10 mL (2 cucharaditas) cada 4 horas	Niños de 6 a 12 años de edad	5 mL (1 cucharadita) cada 4 horas	Niños menores de 6 años	No lo use
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Uses: -Temporarily relieves cough due to the common cold or inhaled irritants. -Helps loosen mucus and bronchial secretions to make cough more productive.	Other Information: Do not use if seal is broken or tam, measure cap is provided. Store at 20°-25°C (68°-77°F).	Usos: -Alivia temporalmente la tos debido a los irritantes inhalados o por resfriados. -Ayuda a aflojar el moco en las bronquias para hacer la tos más productiva.	Otra Información: No utilice el bote si la tapa está rota, evidencias, se proporciona tapa para medir. Almacenar a: 20°-25°C (68°-77°F).																
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 the 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, or persistent headache, these could be signs of a serious condition or illness.	Inactive Ingredients: Pure Honey, Aloe Vera, Eucalyptus, Ginger, Purified water, Citric Acid, Menthol, Potassium Sorbate, Propylene Glycol, Propylparaben, Methylparaben, Sodium Chloride, Sucralose, Hydroxyethylcellulose, Caramel color, Honey flavor.	Advertencias: No usar si está tomando o se está tomando un inhibidor de la monoamina oxidasa (MAOI) o ciertas drogas para la depresión, problemas psiquiátricos, problemas emocionales o enfermedad de Parkinson, o durante 2 semanas después de dejar de tomar el MAOI. Si no sabe si contiene el medicamento MAOI consulte a su médico antes de consumir este producto. Consulte a un profesional de la salud antes de usar este producto si está embarazada o lactando o produce de lactantes. Para el uso y prescripción consulte a su médico si la tos persiste por más de siete días o si se acompaña de fiebre, angustia cada vez o dolor de cabeza persistente, estos pueden ser signos de una afección o enfermedad seria.	Ingredientes Inactivos: Miel Pura, Aloe Vera, Eucalypto, Jengibre, Agua Purificada, Ácido Cítrico, Mentol, Sorbato de Potasio, Propilparabeno, Metilparabeno, Cloruro de Sodio, Sucralosa, Hidroxiethylcelulosa, Color Caramelo, Sabor a miel.																
Keep out of the reach of children, in case of accidental overdose seek professional assistance or contact a Poison Control Center immediately.	LOT: EXP:	Mantener fuera del alcance de los niños, en caso de sobredosis accidente busque ayuda profesional o comuníquese con un centro de información toxicológica.	8 53668 00501 2 Distribuidor exclusivo: ROCKHEALTH, INC. Miami, FL 33018. E-Mail: rockhealth@gmail.com. Quedados o comentarios please call 305-791-8763.																

LIBERA TOS

dextromethorphan hbr, guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60840-0100
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
HONEY (UNII: Y9H1V576FH)	
ALOE (UNII: V5VD430YW9)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GINGER (UNII: C5529G5JPQ)	
WATER (UNII: 059QF0K00R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MENTHOL (UNII: L7T10EIP3A)	

POTASSIUM SORBATE (UNII: 1VPU26JZZ4)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

PROPYLPARABEN (UNII: Z8IX2SC1OH)

METHYLPARABEN (UNII: A2I8C7H9T)

SODIUM CHLORIDE (UNII: 451W47IQ8X)

SUCRALOSE (UNII: 96K6UQ3ZD4)

HYDROXYETHYL CELLULOSE (5500 MPAS AT 2%) (UNII: M825OX60H9)

CARAMEL (UNII: T9D99G2B1R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60840-0100-1	118 mL in 1 BOTTLE		
2	NDC:60840-0100-2	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(60840-0100)

Establishment

Name	Address	ID/FEI	Business Operations
Gadal Laboratories Inc		841305639	MANUFACTURE(60840-0100)

Revised: 11/2013

RockHealth, Inc