LIBERA TOS - dextromethorphan hbr, guaifenes in 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

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 desease), 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 persistant 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 |

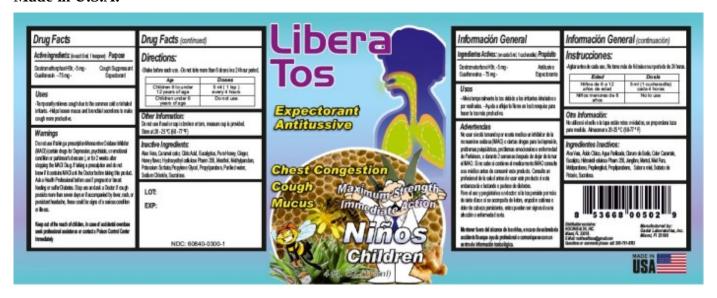
Other Information:Do not use if seal or cap is broken or torn, measure cup is provided Store at 20 - 25 °C (68 - 77 °F).

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 | |
| DEXTRO METHO RPHAN HYDRO BRO MIDE (UNII: 9 D2RTI9 KYH) (DEXTRO METHO RPHAN - 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: V5VD430 YW9) | | | |
| CARAMEL (UNII: T9D99G2B1R) | | | |
| CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP) | | | |
| EUCALYPTUS OIL (UNII: 2R04ONI662) | | | |
| HO NEY (UNII: Y9 H1V576 FH) | | | |
| GINGER (UNII: C5529G5JPQ) | | | |
| HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5) | | | |
| MENTHOL (UNII: L7T10 EIP3A) | | | |

| METHYLPARABEN (UNII: A2I8 C7HI9 T) | |
|--|--|
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| PROPYLENE GLYCOL (UNII: 6 DC9 Q 16 7 V3) | |
| PROPYLPARABEN (UNII: Z8 IX2SC1OH) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| WATER (UNII: 059QF0KO0R) | |
| | |

| 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 | 11/0 1/20 13 | |
| | | | |

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