

DRX CHOICE LONG ACTING COUGH- dextromethorphan hbr liquid RARITAN PHARMACEUTICALS

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.

DRx Choice Long-Acting Cough Drug Facts

Active ingredient (in each 10 mL)

Dextromethorphan HBr, USP 30 mg

Purpose

Cough suppressant

Uses

temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold

Warnings

Do not use

if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, or emphysema

Stop use and ask a doctor if

cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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

1-800-222-1222.

Directions

- do not take more than 4 doses in a 24-hour period
- measure only with dosing cup provided
- keep dosing cup with product
- mL = milliliter
- this adult product is not intended for use in children under 12 years of age

| age | dose |
|---------------------------------------|--------------------------|
| adults and children 12 years and over | 10 mL every 6 to 8 hours |
| children under 12 years | do not use |

Other information

- **each 10 ml contains:** sodium 3 mg
- store at room temperature

Inactive ingredients

anhydrous citric acid, disodium edetate, FD&C red 40, flavor, potassium citrate, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum

Questions or comments?

1-866-467-2748

Principal Display Panel

*Compare to the active ingredient in **Adult Robitussin® Long-Acting Cough***

NDC 68163-742-04

DRx Choice

long-acting

cough

Dextromethorphan HBr (Cough Suppressant)

Relieves: Cough

8 HOURS RELIEF

No Added Alcohol

Sugar-Free

For Ages 12 & Over

4 FL OZ (118mL)

*This product is not manufactured or distributed by Pfizer, owner of the registered trademark Adult Robitussin® Long-Acting Cough.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL ON THE BOTTLE IS BROKEN OR MISSING.

IMPORTANT: Keep this carton for future reference for full labelling.

Manufactured by:

Raritan Pharmaceuticals

8 Joanna Court,

East Brunswick,

NJ 08816



DRX CHOICE LONG ACTING COUGH

dextromethorphan hbr liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68163-742 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------------|-------------------|
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 30 mg in 10 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| POTASSIUM CITRATE (UNII: EE90ONI6FF) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0K00R) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SORBITOL (UNII: 506T60A25R) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:68163-742-04 | 1 in 1 BOX | 04/24/2023 | |
| 1 | | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 04/24/2023 | |

Labeler - RARITAN PHARMACEUTICALS (127602287)

Revised: 5/2023

RARITAN PHARMACEUTICALS