# LITTLE COLDS DECONGESTANT PLUS COUGH- dextromethorphan hydrobromide and phenylephrine hydrochloride liquid Medtech Products 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.

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# Little Colds Decongestant Plus Cough

**Drug Facts** 

# **Active Ingredients**

(in each 1.0 mL)

Dextromethorphan HBr 5mg

# **Purpose**

Cough Suppressant

# **Active Ingredients**

(in each 1.0 mL)

Phenylephrine HCI USP 2.5mg

# Purpose

Nasal Decongestant

#### Uses

Temporarily relieves:

- cough due to minor throat & bronchial irritation as may occur with the common cold
- nasal congestion due to the common cold, hay fever or other respiratory allergies

# **Warnings**

#### Do not use:

- with any other products containing decongestants or cough suppressants. Ask a doctor or pharmacist before using with other drugs if you are not sure.
- Do not give this product to a child who is 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 you are uncertain whether your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

# **Drug Interaction Precaution:**

#### Ask a doctor before use if the child has:

- heart or thyroid disease
- high blood pressure or diabetes

a cough accompanied by excessive phlegm (mucus) or has a persistent or chronic cough such as
occurs with asthma

# When using this product:

#### DO NOT EXCEED RECOMMENDED DOSING.

#### Stop use and ask a doctor if:

- your child becomes nervous, dizzy or sleepless
- symptoms do not get better within 7 days, or are accompanied by fever
- cough persists for more than 7 days, tends to recur, or is accompanied by high fever, rash, or persistent headaches. These could be signs of a serious condition.

# Keep out of reach of children.

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

#### Directions

- Give this medicine by mouth only.
- Only use the enclosed dropper. **Do not use any other dropper, spoon or dosing device when giving this medicine to your child.**
- Fill the enclosed dropper to the prescribed level and slowly dispense the liquid into your child's mouth (towards the inner cheek).
- Do not give more than 6 doses in any 24-hour period (see overdose warning).
- If needed, repeat dose every 4 hours or as directed by a doctor.

Age (yr)	Dose
Under 4	Do not use
4 to under 6	1 mL
6 to under 12	2 mL

# Other Information

- Store at 20-25°C (68-77°F)
- Protect from moisture.
- Oral dosing device enclosed.
- **Tamper Evident:** This product has a foil seal under the cap. Do not use if broken or missing.
- Check expiration date on bottle or box before using.

#### **Inactive Ingredients:**

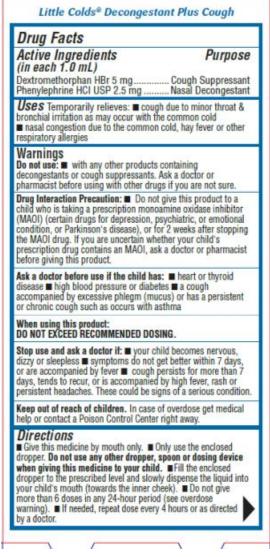
Citric Acid, Glycerin, High Fructose Corn Syrup, Natural Grape Flavor, Purified Water, Sodium Benzoate and Sucralose

#### **Questions?**

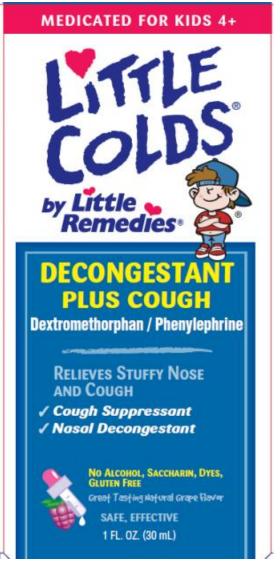
Call **1-800-7-LITTLE** Mon. – Fri. 8:00 a.m. to 8:00 p.m. EST, or visit us online at **www.LittleRemedies.com.** 

#### PRINCIPAL DISPLAY PANEL

Little Colds<sup>®</sup> by Little Remedies<sup>®</sup> DECONGESTANT PLUS COUGH







#### LITTLE COLDS DECONGESTANT PLUS COUGH

dextromethorphan hydrobromide and phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-402
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 1.0 mL
<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1.0 mL

Inactive Ingredients	
Ingredient Name	Strength
CITRIC ACID (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTO SE CORN SYRUP (UNII: XY6 UN3QB6S)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:63029-402-01	1 in 1 BOX		
1	30 mL in 1 BOTTLE, DROPPER		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	09/01/2010	

# Labeler - Medtech Products Inc. (122715688)

Establishment				
Name	Address	ID/FEI	Business Operations	
Denison Pharmaceuticals, Inc.		001207208	MANUFACTURE	

Revised: 10/2010 Medtech Products Inc.