

**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.

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 HCl 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® by Little Remedies®
DECONGESTANT PLUS COUGH

Dextromethorphan/Phenylephrine
RELIEVES STUFFY NOSE AND COUGH
1 FL. OZ. (30 mL)

Little Colds® Decongestant Plus Cough

Drug Facts	
Active Ingredients (in each 1.0 mL)	Purpose
Dextromethorphan HBr 5 mg.....	Cough Suppressant
Phenylephrine HCl USP 2.5 mg.....	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.	
Drug Interaction Precaution: ■ 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.	
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.	

Drug Facts (continued)

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.

MEDICATED FOR KIDS 4+

LITTLE COLDS®

by Little Remedies®

DECONGESTANT PLUS COUGH

Dextromethorphan / Phenylephrine

RELIEVES STUFFY NOSE AND COUGH

✓ Cough Suppressant

✓ Nasal Decongestant

No ALCOHOL, SACCHARIN, DYES, GLUTEN FREE

Great Tasting Natural Grape Flavor

SAFE, EFFECTIVE

1 FL. OZ. (30 mL)

Also Try:

We Make It All Better!®

LITTLE NOSES®

by Little Remedies®

SALINE SPRAY/DROPS

✓ Gentle Moisturizer
✓ No Alcohol
✓ No Side Effects
✓ Use As Often As Needed

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
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 1.0 mL
PHENYLEPHRINE HYDROCHLORIDE (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 FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
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.