

**ADULT LONG LASTING-COUGH RELIEF - dextromethorphan hbr,usp capsule**  
**Chain Drug Consortium LLC**

*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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**ACTIVE INGREDIENT(S)**

Dextromethorphan HBr, USP 15 mg

**PURPOSE**

Cough Suppressant

**USE(S)**

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

**WARNINGS**

**DO NOT USE** 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**

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

**STOP USE AND ASK DOCTOR IF**

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

**PREGNANCY/BREASTFEEDING**

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.

**DIRECTIONS**

- do not take more than 8 liquidgels in any 24-hour period
- **adults and children 12 years and over:** take 2 liquidgels every 6 to 8 hours, as needed
- **children under 12 years:** ask a doctor

**STORAGE**

- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**
- store at 20°-25°C (68°-77°F)
- avoid excessive heat above 40°C (104°F)
- protect from light
- use by expiration date on package

**INACTIVE INGREDIENTS**

Gelatin, Sorbitol, Sorbitan, FD&C Blue No.1, Water, Polyethylene Glycol 400, Povidone K-30, Glycerine, FD&C Red No. 40, Propylene Glycol.

**PRINCIPAL DISPLAY PANEL****CARTON LABEL PDP**

**NDC # 68016-026-20**

**Adult Long-Lasting Cough Relief**  
**DEXTROMETHORPHAN HBr, USP 15mg**  
**COUGH SUPPRESSANT**

**Relieves cough for upto 8 hours**  
**Non-drowsy**  
**Non-Narcotic formula**

**20 softgels**



<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each liquidgel)</b> Dextromethorphan HBr, USP 15 mg.....Cough Suppressant</p> <p><b>Purpose</b></p> <p><b>Use</b> temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold</p> <p><b>Warnings</b> <b>Do not use</b> 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.</p> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>a cough that occurs with too much phlegm (mucus)</li> <li>a cough that lasts or is chronic as occurs with smoking, asthma, or emphysema.</li> </ul> <p><b>Stop use and ask a doctor if</b> cough lasts for more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.</p> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use.</p> <p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.</p>		<p><b>Drug Facts (continued)</b></p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>do not take more than 8 liquidgels in any 24-hour period</li> <li><b>adults and children 12 years and over:</b> take 2 liquidgels every 6 to 8 hours, as needed</li> </ul> <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>take 2 capsules every 6 to 8 hours, as needed</td> </tr> <tr> <td>children under 12 years</td> <td>do not use</td> </tr> </tbody> </table> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li><b>TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING</b></li> <li>store at 20°-25°C (68°-77°F)</li> <li>avoid excessive heat above 40°C (104°F)</li> <li>protect from light</li> </ul> <p><b>Inactive ingredients</b> FD&amp;C blue #1, FD&amp;C red #40, gelatin, glycerin, polyethylene glycol, polydioxane, propyl gallate, propylene glycol, purified water, sorbitol sorbitan, black edible ink.</p> <p><b>Questions or comments?</b> 1-800-xxx-xxxx</p> <p><small>*This product is not manufactured or distributed by Pfizer, Inc., owner of the registered trademark Maximum Strength Unison SleepGels®</small></p>	age	dose	adults and children 12 years and over	take 2 capsules every 6 to 8 hours, as needed	children under 12 years	do not use
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DISTRIBUTED BY: CHAIN DRUG CONSORTIUM, LLC  
3301 BOCA RATON BLVD., SUITE 101 BOCA RATON, FL 33431

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

**PARENTS:**  
Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

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EXP:

## BOTTLE LABEL PDP

NDC # 68016-026-20

**Adult Long-Lasting Cough Relief**  
**DEXTROMETHORPHAN HBr, USP 15mg**  
**COUGH SUPPRESSANT**

**Relieves cough for about 8 hours**  
**Non-Drowsy**  
**Non-Narcotic Formula**

**20 Softgels**



# ADULT LONG LASTING-COUGH RELIEF

dextromethorphan hbr,usp capsule

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-026
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg

## Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

## Product Characteristics

Color	RED	Score	no score
Shape	CAPSULE	Size	13mm
Flavor		Imprint Code	26
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-026-20	1 in 1 CARTON		
1		20 in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	05/22/2013	

**Labeler** - Chain Drug Consortium LLC (101668460)

**Registrant** - Chain Drug Consortium LLC (101668460)

**Establishment**

Name	Address	ID/FEI	Business Operations
Marksans Pharma Limited		925822975	MANUFACTURE(68016-026)

Revised: 5/2013

Chain Drug Consortium LLC