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.

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 USEYou 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 20º-25ºC (68º-77ºF)
- avoid excessive heat above 40ºC (104ºF)
- 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

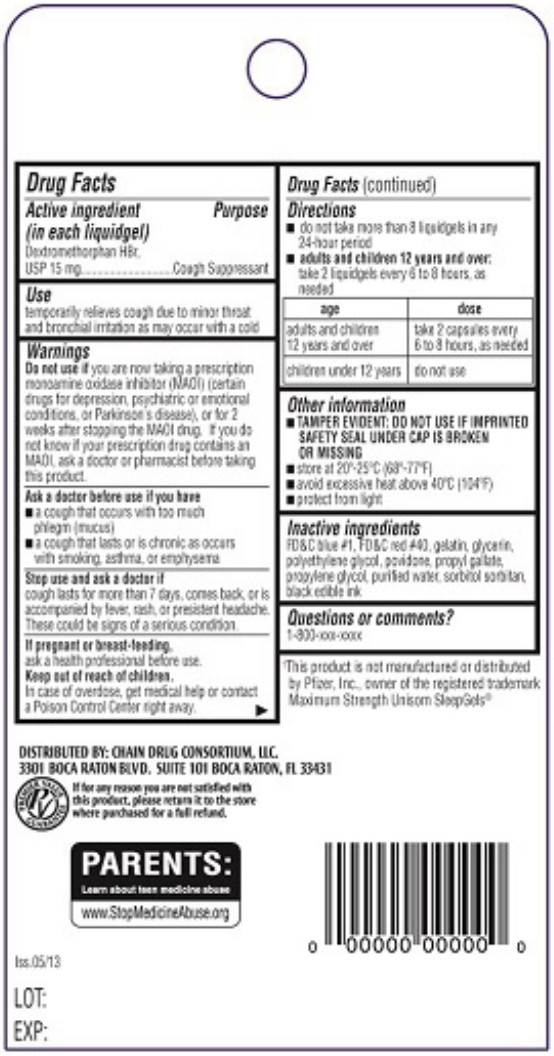
CARTON LABEL PDP

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



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: H3R47K3TBD)	
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