

**DEXTROMETHORPHAN HYDROBROMIDE- dextromethorphan hydrobromide capsule,
liquid filled
SPIRIT PHARMACEUTICALS,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.

Dextrmethorphan Hydrobromide Soft Gelatin Capsules

Drug Facts

Active ingredients (in each LiquiCap)

Dextromethorphan Hbr 15 mg

Purpose

Cough Suppressant

Uses temporarily

relieves cough due to minor throat and bronchial irritation 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

- * a cough that occurs with too much phlegm(mucus)
- * a cough that lasts or is chronic cough 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 conditions

If pregnant or breast-feeding, ask a health professional before use

Keep out of reach of children.

Overdose Warning

In case of overdose,get medical help or contact a poison control center right away.

Direction

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

Other information

- * **each tablet contains** : Store at room temperature

Inactive ingredients

FD &C Red No 40 IH, Polyethylene Glycol , Gelatin, Glycerin, Povidone, Purified water, Sorbitol

PRINCIPAL DISPLAY PANEL - 15mg Tablet Shipper Label**Dextromethorphan Hydrobromide Soft Gelatin Capsules****Each Soft Gelatin Capsules Contains:****Dextromethorphan Hydrobromide USP 15mg**

Lot No. :

Mfg. Date :

Exp. Date :

NDC No. : 68210-1530-4

Quantity : 4000 Capsules

Gross Wt. :

WARNING :**KEEP OUT OF THE REACH OF CHILDREN**

STORE AT CONTROLLED ROOM TEMPERATURE OF 59° - 86°F (15° - 30°C)

PROTECT FROM LIGHT, MOISTURE AND FREEZING

THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY.

CONTENTS SHOULD BE APPROVED,REPACKAGED IMMEDIATELY AND LABELED IN STRICT

CONFORMANCE WITH THE FDAAND REGULATIONS THEREUNDER

MANUFACTURED BY:

Marksans Pharma Ltd

Verna, GOA-403722,

India.

Code : GO/DRUGS/515

MANUFACTURED FOR:

SPIRIT PHARMACEUTICALS,LLC

225 LINCOLN HWY, STE # 205

FAIRLESS HILLS, PA 19030

PH.# 215 943 4000; FAX.#2159434039

OMIL059

CAUTION : "FOR MANUFACTURING, PROCESSING OR REPACKING"

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DEXTROMETHORPHAN HYDROBROMIDE

dextromethorphan hydrobromide capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-1530
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
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GELATIN (UNII: 2G86QN327L)	
POVIDONE (UNII: FZ989GH94E)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	RED	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-1530-4	1 in 1 DRUM		
1		4000 in 1 BAG		
2	NDC:68210-1530-6	1 in 1 DRUM		
2		6000 in 1 BAG		
3	NDC:68210-1530-8	1 in 1 DRUM		
3		8000 in 1 BAG		
4	NDC:68210-1530-1	1 in 1 DRUM		
4		10000 in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/15/2010	

Labeler - SPIRIT PHARMACEUTICALS,LLC (179621011)

Revised: 7/2010

SPIRIT PHARMACEUTICALS,LLC