DEXTROMETHORPHAN HYDROBROMIDE- dextromethorphan hydrobromide capsule, liquid filled
ONE2ZEE LIMITED LIABILITY COMPANY

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.

Drug Facts

Active ingredient (in each softgel)

Dextromethorphan HBr, USP 15mg

Purpose

Cough suppressant

Use

temporarily relieves cough due to minor throat and bronchial irritation as 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 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.

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

Keep out of reach of children. In case of overdose, get medical help orcontact a Poison Control Center right away.

Directions

- do not take more than 8 softgels in any 24-hour period
- this adult product is not intended for use in children under 12 years of age

- adults and children 12 years and over take 2 capsules every 6 to 8 hours, as needed
- children under 12 years do not use

Other information

- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)
- protect from light

Inactive ingredients

polyethylene glycol 400, propylene glycol, povidone k30, fd&c red no. 40, fd&c yellow no. 6, gelatin, glycerin, sorbitol, water

PRINCIPAL DISPLAY PANEL

Dextromethorphan Hydrobromide 15 mg soft gel capsules

Each soft gelatin capsule Contains:- Dextromethorphan Hydrobromide USP.....15 mg

BATCHNO.		QUANTITY	48 X 750 softgels
MFG.DATE		SHIPPER NO.	
EXP.DATE			
NDC NO.	xxxxxxx	GROSS WT.	

WARNING: KEEP OUT OF THE REACH OF CHILDREN

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

THIS IS BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY CONTENTS SHOULD BE APPROVED, REPACKAGED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH THE F.D & C. ACT AND REGULATIONS THEREUNDER.

PROTECT FROM DIRECT SUNLIGHT / MOISTURE / FREEZING

MANUFACTURED BY:

MEDGEL PRIVATE LIMITED
Plot No. 19-20, Special Economic Zone-II (Pharma Zone),
Sector-III, Pithampur, Distt. Dhar-454775, Madhya Pradesh,
India.

MANUFACTURED FOR:

xxxxxxxxxxxxxxxxxxxxxxxxxxxxx

LABELLER CODE : xxxx

MFG. LIC. NO. : xxxxxxxxxxxxxxxxxxxxx

LABELLER CODE : xxxxx

CAUTION: "FOR MANUFACTURING, PROCESSING OR REPACKING"

DEXTROMETHORPHAN HYDROBROMIDE

dextromethorphan hydrobromide capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55629-011
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)	
POVIDONE K30 (UNII: U725QWY32X)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	red	**Score**	no score
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	IS3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55629-011-01	48 in 1 CARTON	02/05/2021	
1	NDC:55629-011-02	750 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/05/2021	

Labeler - ONE2ZEE LIMITED LIABILITY COMPANY (078656111)

Registrant - ONE2ZEE LIMITED LIABILITY COMPANY (078656111)

Establishment

Name	Address	ID/FEI	Business Operations
Medgel Private Limited		677385498	manufacture(55629-011)

Revised: 3/2023

ONE2ZEE LIMITED LIABILITY COMPANY