MUCUS RELIEF DM EXPECTORANT AND COUGH SUPPRESSANT MAXIMUM STRENGTH - guaifenesin and dextromethorphan hbr tablet, extended release Winco Foods, LLC.

Drug Facts

Active ingredients

(in each extended-release tablet)

Dextromethorphan Hydrobromide USP 60 mg Guaifenesin USP 1200 mg

Purpose

Cough suppressant Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
 - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
 - the intensity of coughing
 - the impulse to cough to help you get to sleep

Warnings

Do not use

- for children under 12 years of age
- 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

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough accompanied by too much phlegm (mucus)

When using this product

do not use more than directed

Stop use and ask a doctor if

• cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness.

If pregnant or breast-feeding,

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 (1-800-222-1222) right away.

Directions

- do not crush, chew, or break tablet
- take with a full glass of water
- this product can be administered without regard for timing of meals
- adults and children 12 years and older: 1 tablet every 12 hours; not more than 2 tablets in 24 hours
- children under 12 years of age: do not use

Other information

- tamper evident: do not use if carton is open or if printed seal on blister is broken or missing
- store at 20° to 25°C (68° to 77°F)

Inactive ingredients

colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch (maize)

Questions?

call **800-824-1706** Monday-Friday 9 am - 4 pm MST.

Distributed By: WINCOS FOODS, LLC, BOISE, ID 83704

MADE IN INDIA

*This Product is not manufactured or distributed by RECKITT BENCKISER, Distributor of Maximum Strength MUCINEX®DM.

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1200 mg/60 mg Blister Carton 14 (2 \times 7) Unit-dose Tablets

Comparative to the active ingredients in Maximum Strength Mucinex® DM* Winco® FOODS NDC 67091-315-14

MUCUS RELIEF DM

EXPECTORANT & COUGH SUPPRESSANT Maximum Strength

DEXTROMETHORPHAN HBr 60 MG/ COUGH SUPPRESSANT

GUAIFENESIN 1200 MG/ EXPECTORANT

Controls Cough for 12 Hours Thins and Loosens Mucus 14 Tablets Extended-Release Tablets for 12-Hour Relief



MUCUS RELIEF DM EXPECTORANT AND COUGH SUPPRESSANT MAXIMUM STRENGTH

guaifenesin and dextromethorphan hbr tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-315
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	60 mg	

Inactive Ingredients			
Ingredient Name Strength			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			

MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POVIDONE K90 (UNII: RDH86HJV5Z)		
POVIDONE K25 (UNII: K0KQV10C35)		
STARCH, CORN (UNII: O8232NY3SJ)		

Product Characteristics			
Color	WHITE (white to off-white)	Score	no score
Shape	OVAL	Size	22mm
Flavor		Imprint Code	X;63
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-315- 14	2 in 1 CARTON	03/17/2017	
1		7 in 1 CARTON; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206941	03/17/2017	

Labeler - Winco Foods, LLC. (056098817)

Registrant - Aurohealth LLC (078728447)

Establishment			
Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(67091-315), MANUFACTURE(67091-315)

Revised: 12/2023 Winco Foods, LLC.