MUCUS RELIEF DM MAXIMUM STRENGTH - guaifenesin and dextromethorphan hbr tablet, extended release Better Living Brands 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

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 1-855-274-4122 You may also report side effects to this phone number.

DISTRIBUTED BY BETTER LIVING BRANDS LLC P.O. BOX 99, PLEASANTON, CA 94566-0009 1-888-723-3929 www.betterlivingbrandsLLC.com

MADE IN INDIA

CODE: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1200 mg/60 mg (14 Tablets Blister Carton Label)

Compare to

the active ingredients of Maximum Strength

Mucinex® DM*

NDC 21130-989-65

Signature Care® Quality Guaranteed

MAXIMUM STRENGTH Mucus Relief DM

Guaifenesin and Dextromethorphan HBr Extended-release Tablets 1200 mg/60 mg Expectorant & Cough Suppressant

- Controls Cough
- Thins and Loosens Mucus

12 HOUR ACTUAL SIZE

14 EXTENDED-RELEASE TABLETS



MUCUS RELIEF DM MAXIMUM STRENGTH

guaifenesin and dextromethorphan hbr tablet, extended release

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-989	
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 Strengt		
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:21130-989- 65	2 in 1 CARTON	03/17/2017	
1		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:21130-989- 03	4 in 1 CARTON	04/28/2022	
2		7 in 1 BLISTER PACK; 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 - Better Living Brands LLC (009137209)

Registrant - Aurohealth LLC (078728447)

Establishment			
Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(21130-989), MANUFACTURE(21130-989)

Revised: 2/2024 Better Living Brands LLC