# COUGH AND CONGESTION EXTENDED RELEASE - guaifenesin and dextromethorphan hbr tablet, extended release CVS Pharmacy, Inc.

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#### Drug Facts

### Active Ingredients

(in each extended-release tablet)

Dextromethorphan Hydrobromide USP 30 mg Guaifenesin USP 600 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 or 2 tablets every 12 hours; not more than 4 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.

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# PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 600 mg/30 mg (20 Tablet Carton Label)

CVS Health®

NDC 51316-065-67

COUGH & CONGESTION

GUAIFENESIN, 600 mg DEXTROMETHORPHAN HBr, 30 mg Expectorant / Cough Suppressant

**EXTENDED-RELEASE** 

Controls cough

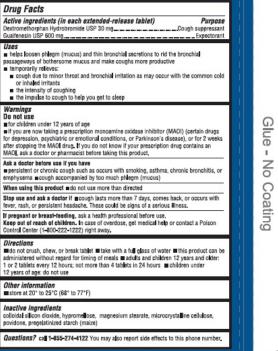
Thins & loosens mucus

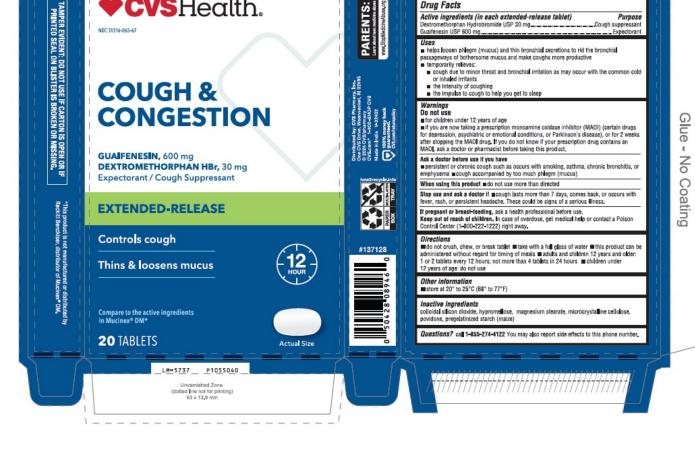
12 HOUR

Compare to the active ingredients in Mucinex® DM\*

**20** TABLETS

**Actual Size** 





Drug Facts

Active ingredients (in each extended-release tablet)

the intensity of coughing
the impulse to cough to help you get to sleep

#### **COUGH AND CONGESTION EXTENDED RELEASE**

quaifenesin and dextromethorphan hbr tablet, extended release

CVSHealth.

**COUGH &** 

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-065
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 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	16mm
Flavor		Imprint Code	X;62
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316- 065-67	2 in 1 CARTON	04/01/2024	
1		10 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	04/01/2024	

### Labeler - CVS Pharmacy, Inc. (062312574)

## Registrant - Aurohealth LLC (078728447)

Establishment			
Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(51316-065), MANUFACTURE(51316-065)

Revised: 6/2024 CVS Pharmacy, Inc.