MUCUS D ER- guaifenes in, pseudoephedrine hydrochloride tablet, extended release Publix Super Markets Inc

Publix Super Markets, Inc. Mucus D●ER Drug Facts

Active ingredients (in each extended-release tablet)

Guaifenesin 600 mg

Pseudoephedrine HCl 60 mg

Purpose

Expectorant

Nasal Decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves nasal congestion due to:
- common cold
- hay fever
- upper respiratory allergies
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- temporarily relieves sinus congestion and pressure

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

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- 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

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days, come back or occur with a 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 right away. (1-800-222-1222)

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: 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 between 20-25°C (68-77°F)
- do not use if blister unit is broken or torn

Inactive ingredients

colloidal silicon dioxide, copovidone, FD&C yellow #6 aluminum lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, sodium starch glycolate, stearic acid

Package/Label Principal Display Panel

12-HOUR

MUCUS D●ER

GUAIFENESIN 600 mg / PSEUDOEPHEDRINE HYDROCHLORIDE 60 mg

EXTENDED-RELEASE TABLETS

EXPECTORANT/NASAL DECONGESTANT

ACTUAL SIZE

Clears Nasal/Sinus Congestion

Thins and Loosens Mucus

18 EXTENDED-RELEASE TABLETS

Compare to the Active Ingredients in Mucinex® D



MUCUS D ER

guaifenesin, pseudoephedrine hydrochloride tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-144
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg	
PSEUDO EPHEDRINE HYDRO CHLO RIDE (UNII: 6 V9 V2RYJ8 N) (PSEUDO EPHEDRINE - UNII:7CUC9 DDI9 F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg	

Inactive Ingredients	
Ingredient Name	Strength

SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
COPOVIDONE K25-31 (UNII: D9 C330 MD8 B)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
PO VIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	ORANGE (peach)	Score	no score
Shape	OVAL (biconvex)	Size	18 mm
Flavor		Imprint Code	600;Watson
Contains			

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-144-89	18 in 1 CARTON	06/23/2016	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:56062-144-68	36 in 1 CARTON	06/23/2016	
2		1 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	ANDA091071	06/23/2016	

Labeler - Publix Super Markets Inc (006922009)

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