

MUCUS RELIEF XPECT- guaifensin, dextromethorphan tablet

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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.

XL3 Xpect Mucus Relief

Active ingredients (in each tablet)

Guaifenesin 400mg

Dextromethorphan HBr 20mg

Purposes

Expectorant

Cough suppressant

Uses

■ helps loosen phlegm (mucus) ■ helps thin bronchial secretions to make coughs more productive ■ temporarily relieves cough due to minor sore throat and bronchial irritation associated with the common 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 a MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

■ cough accompanied by excessive phlegm (mucus) ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema.

Ask a doctor or pharmacist before use if you

■ are taking sedatives or tranquilizers.

Stop use and ask a doctor if

■ cough lasts for more than 7 days, recurs, or is accompanied by fever, rash, or persistent headache.

These could be signs of a serious condition.

Pregnancy/Breastfeeding

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

Keep out of reach of children

Keep out of the reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years and older: take 1 tablet every 4 hours with a full glass of water while symptoms persist. ■ Do not exceed 6 doses in 24 hours. **Children under 12 years of age:** do not use.

Other information

■ store at 25°C (77°F) excursions between 15°-30°C (59°-86°F) ■ Keep in a dry place and do not expose to heat ■ do not use if blister package is torn or damaged.

Inactive Ingredients

alcohol, colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate (derived from milk), magnesium stearate, polyethylene glycol, povidone, purified water, stearic acid

Questions or Comments?

Call toll free 1-855-259-1590 Monday through Friday 9 AM - 5 PM EST.

Package Label



MUCUS RELIEF XPECT

guaifenesin, dextromethorphan tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63654-342
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0KO0R)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	XL3;XPECT
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63654-342-20	2 in 1 CARTON	05/19/2021	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63654-342-30	3 in 1 CARTON	05/19/2021	
2		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
OTC monograph final	M012	05/17/2021	

