DEXTROMETHORPHAN HBR AND GUAIFENESIN- dextromethorphan hbr and guaifenesin solution
Hi-Tech Pharmacal Co., Inc.

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.

Drug Facts

Active ingredient

Each 5 mL (1 teaspoonful) contains:

Dextromethorphan HBr .....10 mg

Guaifenesin .....100 mg

Inactive ingredients

Acesulfame potassium, artificial cherry & vanilla flavor, aspartame, hypromellose, menthol, methylparaben, potassium sorbate, purified water. Citric acid may be used to adjust pH.

Purpose

Cough Suppressant

Expectorant

Uses

- temporarily relieves cough
- helps loosen phlegm (mucus) and thin bronchial secretions to rid bronchial passageways of bothersome mucus

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 two 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

- a cough that occur with too much phlegm (mucus)
- a chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Stop use and ask a doctor if

- a cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts These could be signs of a serious condition.

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.

Professional note: Guaifenesin has been shown to produce a color interference with certain clinical laboratory determinations of 5- hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

Directions

- take every 4 hours
- do not exceed 6 doses in 24 hours

Age	Dose
Adults & children 12 years & over	10 mL (2 teaspoonfuls)
Children 6 years to under 12 years	5 mL (1 teaspoonful)
Children 2 years to under 6 years	2.5 mL (1/2 teaspoonful)
Children under 2 years	Ask a doctor

How Supplied: Dextromethorphan HBr and Guaifenesin Oral Solution is a clear viscous liquid with a slight cherry odor supplied in the following oral dosage forms: 5 mL unit dose, 10 mL unit dose in trays of 10 and 4 fl. oz. (118 mL) bottle

Phenylketonurics: contains phenylalanine 8.4 mg per teaspoonful (5 mL)

Storage: Keep tightly closed. Store at controlled room temperature 20-25° C (68-77°F). [See USP] Protect from light.

QUESTIONS OR COMMENTS?

Call **1-800-262-9010**.

Hi-Tech Pharmacal Co., Inc.

Amityville, NY 11701

Rev.062:00 10/10

MG #29851

Package/Label Principal Display Panel

Delivers 10 mL

NDC 50383-062-10

DEXTROMETHORPHAN HBr & GUAIFENESIN ORAL SOLUTION

20 mg/200 mg per 10 mL

Sugar Free/Alcohol Free

COUGH SUPPRESSANT/EXPECTORANT

SEE INSERT

FOR INSTITUTIONAL USE ONLY

Hi-Tech Pharmacal Co., Inc.

Amityville, NY 11701

Rev. 062:00 10/10

DEXTROMETHORPHAN HBR AND GUAIFENESIN

dextromethorphan hbr and guaifenesin solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50383-062
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ASPARTAME (UNII: Z0H242BBR1)	
HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN3152OP35)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	CHERRY (artificial cherry flavor) , VANILLA (artificial vanilla flavor)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50383-062-06	4 in 1 CASE		
1	NDC:50383-062-05	10 in 1 TRAY		
1		5 mL in 1 CUP, UNIT-DOSE		
2	NDC:50383-062-07	10 in 1 CASE		
2		10 in 1 TRAY		
2		5 mL in 1 CUP, UNIT-DOSE		
3	NDC:50383-062-11	4 in 1 CASE		
3	NDC:50383-062-10	10 in 1 TRAY		
3		10 mL in 1 CUP, UNIT-DOSE		
4	NDC:50383-062-12	10 in 1 CASE		
4		10 in 1 TRAY		
4		10 mL in 1 CUP, UNIT-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/07/2012	

Labeler - Hi-Tech Pharmacal Co., Inc. (101196749)

Establishment

Name	Address	ID/FEI	Business Operations
Hi-Tech Pharmacal Co., Inc.		101196749	MANUFACTURE(50383-062)

Revised: 3/2013 Hi-Tech Pharmacal Co., Inc.