BALAHIST DM SYRUP- brompheniramine maleate, phenylephrine hydrochloride, dextromethorphan hydrobromide liquid
Ballay Pharmaceuticals, 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.

Balahist DM Syrup

Drug Facts

Active Ingredients

(in each 5 mL teaspoonful)

Brompheniramine Maleate, USP 4 mg

Dextromethorphan HBr, USP 15 mg

Phenylephrine HCl, USP 7.5 mg

Purposes

Chlorpheniramine Maleate	Antihistamine
Dextromethorphan HBr	Cough Suppressant
Phenylephrine HCl	Nasal Decongestant

Uses

temporarily relieves these symptoms due to the common cold, hay fever or other upper respiratory allergies:

- runny nose
- nasal congestion
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- relieves cough 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, 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
- glaucoma
- a breathing problem, or persistent or chronic cough such as occurs with smoking, asthma, emphysema or chronic bronchitis
- cough accompanied by excessive phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland.

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- **Do not exceed recommended dosage**
- excitability may occur, especially in children
- marked drowsiness may occur; alcohol, sedatives and tranquilizers may increase the drowsiness effect
- use caution when driving a motor vehicle or operating machinery
- avoid alcoholic beverages.

Stop use and ask a doctor if

- new symptoms occur
- nervousness, dizziness, or sleeplessness occur
- cough or nasal congestion persists for more than 7 days, tends to recur, or is accompanied by fever, rash, or persistent headache. 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.

Directions

- **do not exceed 6 doses in a 24 hour period**

adults and children 12 years of age and over	1 teaspoonful (5 mL) every 4 to 6 hours
children 6 years to under 12 years of age	1/2 teaspoonful (2.5 mL) every 4 to 6 hours
children under 6 years of age	ask a doctor

Other information

- **do not use if tamper evident seal under cap is broken or missing**
- store between 20° - 25° C (68° - 77° F).

Inactive Ingredients

citric acid, glycerin, purified water, sodium benzoate, sodium citrate, sorbitol, strawberry flavor.

Questions?

call 1-800-847-1921

Manufactured by:
Ballay Pharmaceuticals, Inc.
Wimberley, Texas 78676

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label
NDC 63162-520-16
Balahist DM
Syrup
Antihistamine/Decongestant/
Antitussive(Cough Suppressant)
Each teaspoonful (5 mL) for oral
administration contains:
Brompheniramine
Maleate ..... 4 mg
Dextromethorphan
Hydrobromide ..... 15 mg
Phenylephrine
Hydrochloride ..... 7.5 mg

For Professional Use Only
Sugar Free/Alcohol Free/
Dye Free
BALLAY 16 fl oz.(473 mL)

BALAHIST DM SYRUP

brompheniramine maleate, phenylephrine hydrochloride, dextromethorphan hydrobromide liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63162-520
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BROMPHENIRAMINE MALEATE (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	4 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	7.5 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63162-520-16	473 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/06/2014	

Labeler - Ballay Pharmaceuticals, Inc. (035888200)

Establishment

Name	Address	ID/FEI	Business Operations
Ballay Pharmaceuticals, Inc.		035888200	manufacture(63162-520)

Revised: 11/2013 Ballay Pharmaceuticals, Inc.