

BIO DTUSS DMX- brompheniramine maleate, dextromethorphan, pseudoephedrine liquid
Advanced Generic Corporation

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 Ingredients (in each 5 mL tsp.)	Purpose
Brompheniramine Maleate..... 1mg	Antihistamine
Dextromethorphen HBr..... 20 mg	Cough Suppressant
Pseudoephedrine HCl..... 30mg	Nasal Decongestant

Uses:

- Temporarily relieves cough due to minor throat and bronchial irritation as may occurring with a cold, and nasal congestion due to the common cold, hay fever or other upper respiratory allergies or associated with sinusitis
- Temporarily relieves these symptoms due to hay fever(allergies rhinitis)
- Runny nose
- Sneezing
- Itchy, watery eyes
- Itchy of the nose or throat
- Temporarily restores free breathing through the nose

Warnings:

- May cause excitability especially in children. May cause drowsiness, alcohol, sedatives and tranquilizers may increase the drowsiness effect. Avoid alcohol beverages while taking this product. Do not take this product if you have taken sedatives or tranquilizers, without first consulting your doctor. Use caution when driving a motor vehicle or operating machinery.
- Do not exceed recommended dosage. 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 you are taking a prescription drug that contains an MAOI; ask your doctor or pharmacist before taking this product.

Do Not Use:

Ask a doctor before use if you have:

- Cough that occurs with too much phlegm (mucus)
- Heart disease
- High blood pressure
- Thyroid disease
- Diabetes
- Glaucoma
- Trouble urinating due to an enlarged prostate gland
- A breathing problem or persistent or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema

Stop use and ask a doctor if:

- You get nervous, dizzy or sleepless
- Symptoms do not get better within 7 days, comes back, or is accompanied by fever, rash or persistent headache. These could be signs of a serious condition

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

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

Directions:

adults and children 12 years of age and over	take 1 teaspoonfull every 6 hours
children 6 to under 12 years of age	take 1/2 teaspoonfull every 6 hours
children under 6 years of age	ask doctor

Other Information:

store at room temperature 15-30 degrees celcius (59-86 degrees fahrenheit)

Tamper Evident Feature Do not use if seal under cap(or cello band over cap) is torn, broken or missing

Inactive Ingredients:

Glycerin, Propylene Glycol, Methylparaben, Propylparaben, Sucrose, Citric Acid, Sodium Citrate, D and C Red #33, FD and C Blue #1, Grape Flavor and Purified Water.

Question and Comments? 1-305-403-3788

Advanced Generic Corporation, Miami, FL 33166

www.advancedgeneric.com

Drug Facts

Active ingredients (in each 5 mL tsp.) Purpose
 Brompheniramine Maleate USP..... 1 mg.....Antihistamine
 Dextromethorphan HBr, USP.....20 mg.....Cough Suppressant
 Pseudoephedrine HCl, USP.....30 mg.....Nasal Decongestant

Uses temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold, and nasal congestion due to the common cold, hay fever or other upper respiratory allergies or associated with sinusitis temporarily relieves these symptoms due to hay fever (allergic rhinitis) runny nose sneezing itchy, watery eyes itchy of the nose or throat temporarily restores free breathing through the nose.

Warnings May cause excitability especially in children. May cause drowsiness, alcohol, sedatives and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take this product if you have taken sedatives or tranquilizers, without first consulting your doctor. Use caution when driving a motor vehicle or operating machinery.

Do not exceed recommended dosage 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 you are taking a prescription drug that contains an MAOI, ask your doctor or pharmacist before taking this product.

Ask a doctor before use if you have
 cough that occurs with too much phlegm (mucus) heart disease high blood pressure thyroid disease diabetes glaucoma trouble urinating due to an enlarged prostate gland a breathing problem or persistent or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema.
 †Deltuss® DMX is a trademark of Deliz Pharmaceutical Corp.

Lot #: 12/10
 Exp. Date:

NDC 45737-203-16

BIO-Dtuss DMX

- Antihistamine
- Cough Suppressant
- Nasal Decongestant

Alcohol FREE

Contains the same active ingredients as
 Deltuss® DMX†

Grape Flavor

Manufactured For:



advanced generic corporation
 Miami, FL 33166
 www.advancedgeneric.com

16 fl. oz. (473 mL)

Drug Facts (continued)

Stop use and ask a doctor if you get nervous, dizzy or sleepless symptoms do not get better within 7 days or is accompanied by fever cough lasts more than 7 days, comes back, 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 take more than 4 doses in 24 hour period.

adults and children 12 years of age and over	take 1 teaspoonfull every 6 hours
children 6 to under 12 years of age	take 1/2 teaspoonfull every 6 hours
children under 6 years of age	ask a doctor

Other information

store at room temperature 15°-30°C (59°-86°F).
Tamper Evident Feature Do not use if seal under cap (or cello-band over cap) is torn, broken or missing.

Inactive ingredients Glycerin, Propylene Glycol, Methylparaben, Propylparaben, Sucrose, Citric Acid, Sodium Citrate, D&C Red#33, FD&C Blue #1, Grape Flavor and Purified Water.

Questions or comments? 1-305-403-3788

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**BIO DTUSS DMX**

brompheniramine maleate, dextromethorphan, pseudoephedrine liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45737-203
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BROMPHENIRAMINE MALEATE (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	1 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 5 mL
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SUCROSE (UNII: C15IH8M554)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE (Grape Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45737-203-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/01/2011	

Labeler - Advanced Generic Corporation (831762971)**Registrant** - Advanced Generic Corporation (831762971)

Revised: 12/2020

Advanced Generic Corporation