

ABATUSS DMX- dexchlorpheniramine maleate, dextromethorphan hydrobromide, pseudoephedrine hydrochloride liquid
Kramer Novis

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.

ABATUSS DMX Antihistamine Cough Suppressant Nasal Decongestant GRAPE Flavor

Drug Facts

Active ingredients (per 5 mL)

Dexchlorpheniramine Maleate 1 mg
Dextromethorphan HBr 15 mg
Pseudoephedrine HCl 30 mg

Purpose

Antihistamine
Cough Suppressant
Nasal Decongestant

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- sneezing
- itchy nose or throat
- runny nose
- itchy, watery eyes
- nasal congestion
- temporarily controls cough due to minor throat and bronchial irritation associated with inhaled irritants
- temporarily restores freer breathing through nose

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 • a breathing problem such as emphysema or chronic bronchitis • glaucoma • difficulty in urination due to enlarged prostate gland • persistent or chronic cough such as occurs with smoking, asthma, or emphysema • cough accompanied by excessive phlegm (mucus)

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

When using this product • do not exceed recommended dosage • may cause drowsiness • alcohol, sedatives, and tranquilizers may increase the drowsiness effect • avoid alcoholic beverages • use caution when driving a motor vehicle or operating machinery marked may occur • excitability may occur especially in children

Stop use and ask a doctor if • nervousness, dizziness, or sleeplessness occur • cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition. • symptoms do not improve within 7 days or are accompanied by fever

If pregnant or breastfeeding 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:

| | |
|---|---|
| Adults and children 12 years of age and older | 2 teaspoonfuls (10 mL) every 6 hours, not to exceed 8 teaspoonfuls in 24 hours or as directed by a doctor |
| Children 6 to under 12 years of age | 1 teaspoonful (5 mL) every 6 hours, not to exceed 4 teaspoonfuls in 24 hours or as directed by a doctor |
| Children 2 to under 6 years of age | Consult a doctor |

Other information

- Store at controlled room temperature 15°C-30°C (59°F-86°F)
- Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing

Inactive ingredients:

Citric acid, FD&C blue #1, FD&C Red #40, grape flavor, methylparaben, monoammonium glycyrrhizinate, potassium citrate, potassium sorbate, propylene glycol, propylparaben, purified water, sorbitol, sucralose.

*Contains the same active ingredients as Deltuss DMX®

**Antihistamine
Cough Suppressant
Nasal Decongestant**

Each 5 mL contains:

Dexchlorpheniramine Maleate1 mg
Dextromethorphan HBr.....15 mg
Pseudoephedrine HCl30 mg

• **Alcohol Free** • **Sugar Free**

• **Gluten Free**

Grape Flavor

Manufactured in the USA for Kramer Novis, San Juan, PR 00917. T: (787) 767-2072
www.kramernovis.com

* Deltuss DMX® is a registered trademark of Deliz Pharmaceutical Corp. This product is not manufactured, distributed or marketed by Deliz Pharmaceutical Corp.

Packaging

NDC 52083-625-16

Abatuss DMX

*Contains the same active ingredients as Deltuss DMX®

Antihistamine Cough Suppressant Nasal Decongestant

Each 5 mL contains:
Dexchlorpheniramine Maleate 1 mg
Dextromethorphan HBr 15 mg
Pseudoephedrine HCl 30 mg

- Alcohol Free • Sugar Free
- Gluten Free

Grape Flavor

16 fl oz (473 mL)

Manufactured in the USA for
Kramer Novis, San Juan, PR 00917.
T: (787) 767-2072 www.kramernovis.com



Drug Facts

Active Ingredients (per 5 mL)

| | |
|----------------------------------|--------------------|
| Dexchlorpheniramine Maleate 1 mg | Antihistamine |
| Dextromethorphan HBr 15 mg | Cough Suppressant |
| Pseudoephedrine HCl 30 mg | Nasal Decongestant |

Purpose

Uses
temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ itchy nose or throat ■ runny nose ■ itchy, watery eyes ■ nasal congestion ■ temporarily controls cough due to minor throat and bronchial irritation associated with inhaled irritants ■ temporarily restores freer breathing through nose

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 ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ difficulty in urination due to enlarged prostate gland ■ persistent or chronic cough such as occurs with smoking, asthma, or emphysema ■ cough accompanied by excessive phlegm (mucus)

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

When using this product ■ do not exceed recommended dosage ■ may cause drowsiness ■ alcohol, sedatives, and tranquilizers may increase the drowsiness effect ■ avoid alcoholic beverages ■ use caution when driving a motor vehicle or operating machinery ■ excitability may occur especially in children

Stop use and ask a doctor if ■ nervousness, dizziness, or sleeplessness occur ■ cough persists for more than

Drug Facts (continued)

1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition. ■ symptoms do not improve within 7 days or are accompanied by fever

If pregnant or breastfeeding 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:

| | |
|---|---|
| Adults and children 12 years of age and older | 2 teaspoonfuls (10 mL) every 6 hours, not to exceed 8 teaspoonfuls in 24 hours or as directed by a doctor |
| Children 6 to under 12 years of age | 1 teaspoonful (5 mL) every 6 hours, not to exceed 4 teaspoonfuls in 24 hours or as directed by a doctor |
| Children 2 to under 6 years of age | Consult a doctor |

Other information

- Store at controlled room temperature 15°C-30°C (59°F-86°F)
- Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing

Inactive ingredients: Citric acid, FD&C blue #1, FD&C red #40, grape flavor, methylparaben, monoammonium glycyrrhizinate, potassium citrate, potassium sorbate, propylene glycol, propylparaben, purified water, sorbitol, sucralose

*Deltuss DMX® is a registered trademark of Deliz Pharmaceutical Corp. This product is not manufactured, distributed or marketed by Deliz Pharmaceutical Corp.

Rev. 07/18



N 3 52083-62516 9

ABATUSS DMX

dexchlorpheniramine maleate, dextromethorphan hydrobromide, pseudoephedrine hydrochloride liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52083-625 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------------------|------------------|
| DEXCHLORPHENIRAMINE MALEATE (UNII: B10YD955QW) (DEXCHLORPHENIRAMINE - UNII:3Q9Q0B929N) | DEXCHLORPHENIRAMINE MALEATE | 1 mg in 5 mL |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 15 mg in 5 mL |
| PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F) | PSEUDOEPHEDRINE HYDROCHLORIDE | 30 mg in 5 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C) | |
| POTASSIUM CITRATE (UNII: EE90ONI6FF) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZ4) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| WATER (UNII: 059QF0KO0R) | |
| SORBITOL (UNII: 506T60A25R) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |

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:52083-625-16 | 1 in 1 CARTON | 05/25/2014 | |
| 1 | | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 05/25/2014 | |

Labeler - Kramer Novis (090158395)

Registrant - Kramer Novis (090158395)

Revised: 10/2022

Kramer Novis