ABANATUSS PED DROPS- chlophedianol hydrochloride, dexchlorpheniramine maleate, pseudoephedrine hydrochloride solution
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.

ABANATUSS *PED DROPS*

Drug Facts

Active Ingredients (in each 1 mL)

Chlophedianol HCL, 6.25 mg

Dexchlorpheniramine Maleate, 0.5 mg

Pseudoephedrine HCL, 15 mg

Purpose

Cough Suppressant

Antihistamine

Nasal Decongestant

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

Uses

- temporarily calms cough due to minor throat and bronchial irritation as may occur with the common cold
- calms the cough control center and relieves coughing
- non narcotic cough suppressant for the temporary relief of cough
- controls cough impulse without narcotics
- temporarily relieves runny nose and alleviates sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever or other respiratory allergies.
- temporarily relieves nasal congestion due to the common cold
- helps decongest sinus opening and passages; temporarily relieves sinus congestion and pressure

Warnings

- **Do not use** in a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if your child has

- diabetes
- heart disease
- thyroid disease
- high blood pressure
- cough that occurs with too much phlegm (mucus)

- cough that lasts or is chronic such as occurs with asthma, chronic bronchitis or emphysema.
- breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if your child is taking sedatives or tranquilizers

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

Stop use and ask a doctor if nervousness, dizziness, or sleeplessness occur
- symptoms do not get better within 7 days or are accompanied by fever
- coughs lasts more than 7 days, comes back, or is accompanied by fever, rash, or a persistent headache.

These could be signs of a serious condition.

Directions • do not take more than 4 doses in any 24-hour period

Age	Dose
Children 6 to under 12 years of age	2 mL every 6 hours (Two Dropperful)
Children under 6 years of age	Consult physician

Inactive ingredients citric acid, flavors, propylene glycol, sodium benzoate, sorbitol, sucralose and water

Other information
- Store at controlled room temperature 15-30°C (59-86°F)
- protect from freezing
- protect from light
- avoid excessive heat or humidity.
- TAMPER EVIDENT: Do not use this product if printed inner cap seal is broken or missing.

RETAIN CARTON FOR FULL PRESCRIBING INFORMATION

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

*** Panatuss® PED Drops is a registered trademark of Seyer Pharmatec. This product is not manufactured, distributed or marketed by Seyer Pharmatec.**

Contains the same active ingredients as Panatuss® PED Drops*

SUGAR FREE • DYE FREE

ALCOHOL FREE • GLUTEN FREE

TROPICAL FRUIT FLAVOR

Packaging

ABANATUSS PED DROPS

chlophedianol hydrochloride, dexchlorpheniramine maleate, pseudoephedrine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52083-685
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

CHLOPHEDIANOL HYDROCHLORIDE (UNII: 69QQ58998Y) (CHLOPHEDIANOL - UNII:42C50P12AP)	CHLOPHEDIANOL HYDROCHLORIDE	6.25 mg in 1 mL
DEXCHLORPHENIRAMINE MALEATE (UNII: B10YD955QW) (DEXCHLORPHENIRAMINE - UNII:3Q9Q0B929N)	DEXCHLORPHENIRAMINE MALEATE	0.5 mg in 1 mL
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	15 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	FRUIT (Tropical fruit)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-685-01	1 in 1 CARTON	08/05/2015	
1		30 mL in 1 BOTTLE, PLASTIC; 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	08/05/2015	

Labeler - KRAMER NOVIS (090158395)

Registrant - KRAMER NOVIS (090158395)

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