PANATUSS PEDIATRIC DROPS DXP - dexbrompheniramine maleate, dextromethorphan, phenylephrine liquid
Seyer Pharmatec, 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 Ingredients (per 1 mL)	**Purpose**
Dexbrompheniramine Maleate 0.5 mg	Antihistamine
Dextromethorphan HBr 5 mg	Cough Suppressant
Phenylephrine HCl 2.5 mg	Nasal Descongestant

Uses

- Temporarily relieves cough due to minor throat and bronchial irritations as may occur with the common cold.
- Temporarily relieves nasal congestions due to common cold.
- For temporary relief of runny nose, sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever or allergic rhinitis.

Warnings:

Do not use: in child who is taking a prescription monoamine oxidase inhibitor (MAOI), (certain drugs for prescription, 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. May cause excitability especially in children. Do not take this product, if you have a breathing problem such as emphysema or chronic bronchitis, glaucoma, heart disease, high blood pressure, diabetes, or thyroid disease, unless directed by a doctor. May cause drowsiness; alcohol, sedatives and tranquilizers may increase the drowsiness effect. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor.

When using this product:

- Use only as directed by physician

Stop use and ask a doctor if

- Your child gets nervous, dizzy, or sleepless
- Condition lasts for more than 7 days, comes back, or is accompanied by fever, rash or persistent headache. These could be signs of a serious condition.

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

If pregnant or breast feeding, consult a doctor.

Directions

- To be taken by mouth only. Not for nasal use.

- Children 6 years of age to under 12 years; 2 mL every 4 - 6 hours.
- Children under 6 years of age: Consult a doctor.
- Do not exceed 4 doses in 24 hours.

Other Information:

- Warning: Phenylketonorics contains phenylalanine 1.5 mg per 1 mL
- Store at 15-30 degrees celcius(59-86 degrees fahrenheit)
- Alcohol Free and Phenylpropanolamine (PPA) Free
- Wrapped calibrated syringe (enclosed)

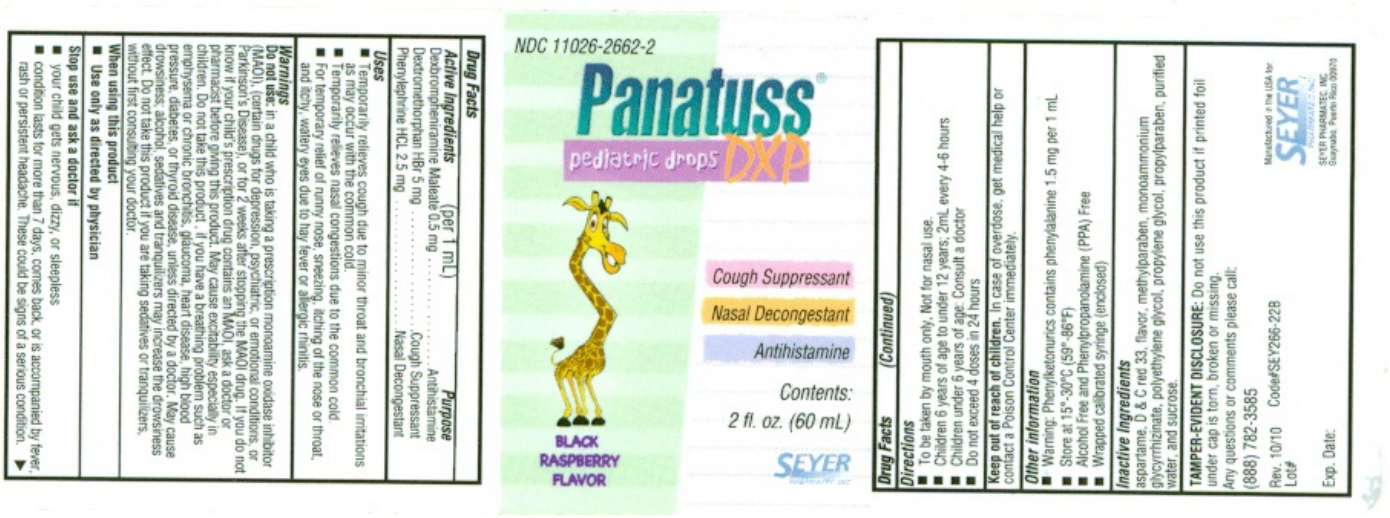
TAMPER-EVIDENT DISCLOSURE: Do not use this product if printed foil under cap is torn, broken or missing.

Inactive Ingredients

aspartame, D and C red 33, flavor, methylparaben, monoammonium glycyrrhizinate, polyethylene glycol, propylene glycol, propylparaben, purified water, and sucrose.

Any questions or comments please call: (888) 782 - 3585

Seyer Pharmatec, Inc. Guaynabo, Puerto Rico 00970



PANATUSS PEDIATRIC DROPS DXP

dexbrompheniramine maleate, dextromethorphan, phenylephrine liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11026-2662
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXBROMPHENIRAMINE MALEATE (UNII: BPA9UT29BS) (DEXBROMPHENIRAMINE - UNII:75T64B71RP)	DEXBROMPHENIRAMINE MALEATE	0.5 mg in 1 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 1 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
GLYCYRRHIZIN, AMMONIATED (UNII: 3VRD35U26C)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11026-2662-2	60 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/01/2005	

Labeler - Seyer Pharmatec, Inc. (832947126)

Registrant - Seyer Pharmatec, Inc. (832947126)

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