NOVALGINA PEDIATRICO COUGH AND COLD PEDIATRICO- dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid
HBC Pharma LLC

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.

Novalgina Pediatrico Cough and Cold

Active Ingredients:(in each 1 ml.)	Purpose
Dextromethorphan Hydrobromide 7.5 mg	Cough Suppressant
Guaifenesin 88 mg.....	Expectorant
Phenylephrine HCl 2.5 mg.....	Decongestant

Uses:

- Helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make the cough more productive.
- Temporarily relieves cough due to minor throat and bronchial irritation as may occur with the common cold. or inhaled irritants
- the intensity of coughing
- The impulse to cough to help your child get to sleep
- nasal congestion due to a cold
- stuffy nose

Warnings

in a child who is taking 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.

Do not Use

in a child who is taking 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

Ask a doctor before use if the child has

- Heart disease
- high blood pressure
- thyroid disease
- diabetes
- persistent or chronic cough such as occurs with asthma

- cough that occurs with too much phlegm (mucus)

When using this product

When using this product do not use more that directed

Stop use and ask a doctor

If nervousness, dizziness, or sleeplessness occur symptoms do not get better within 7 days or occur with fever cough last more than 7 days, comes back, or occurs with 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.

Other Information:

Each 1 mls

Store between 15 - 30 degrees Celsius (59 - 86 Fahrenheit).

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- Tamper Evident Feature: Do not use if there is evidence of tampering

Inactive Ingredient

Citric Acid, FD&C red no. 40, artificial flavors, glycerine, high fructose corn syrup, Hydroxyethyl Cellulose, methylparaben, propylene glycol, Propylparaben, purified water, sodium citrate, sorbitol solution, sucralose.

Dosage and Administration

Do not exceed recommended dose. Measure with the dosage device provided

Children 6 to under 12 years of age 2 ml every 6-8 hours
Children 2 to under 6 years of age 1 ml every 6-8 hours
Children under 2 years of age Consult a doctor

Novalgina
PEDIÁTRICO
ANTIFACTION
Drug Facts

Drug Facts (continued)

NOVALGINA PEDIATRICO COUGH AND COLD PEDIATRICO

dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83057-0002
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	7.5 mg in 1 mL

GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	88 mg in 1 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83057-0002-2	1 in 1 CARTON	02/01/2023	
1		60 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	02/01/2023	

Labeler - HBC Pharma LLC (063580631)

Establishment

Name	Address	ID/FEI	Business Operations
GADAL Laboratories, Inc		841305639	manufacture(83057-0002)

Revised: 10/2023 HBC Pharma LLC