

**NOVALGINA CHILDREN COUGH AND COLD- acetaminofen, 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.*

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**Novalgina Children Cough and Cold**

Active Ingredients:(in each 10 ml.)	Purpose
Acetaminophen 250 mg .....	Analgesic
Dextromethorphan Hydrobromide 13.33 mg .....	Cough Suppressant
Guaifenesin USP 200 mg.....	Expectorant
Phenylephrine HCl 5 mg.....	Decongestant

**Uses:**

- For temporary relief of Bronchial and Nasal congestion
- Helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make cough more productive.
- Temporarily relieves cough due to minor throat and bronchial irritation as may occur with the common cold.

**Warnings**

Do not exceed recommended dosage

**Liver Warning** this product contains Acetaminophen. Severe liver damage may occur if

- Adult takes more than 6 doses in 24 hours, which is the maximum daily amount
- Child takes more than 5 doses in 24 hours
- Taken with other drugs containing Acetaminophen.
- Adult has 3 or more alcoholic drinks every day while using this product
- Do not give to children under 3 years of age or use for more than 10 days unless directed by a physician
- Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric conditions, or Parkinson's disease) or for 2 weeks after stopping MAOI drug.
- If you do not know if your prescription drug contains MAOI as your doctor or pharmacist before taking this product.
- If you have a chronic pulmonary disease or shortness of breath unless directed by a doctor.
- Avoid alcoholic beverage while taking this product.
- Do not use with any other drug containing Acetaminophen (prescription or nonprescription) If you are not sure whether a drug contains Acetaminophen, ask a doctor or pharmacist

**Stop use and ask a doctor**

- Nervousness, dizziness or sleeplessness occurs.
- Cough persists more than 1 week, tends to recur or is accompanied by a fever, rash or persistent headache. A persistent cough may be a sign of a serious condition.

**Ask doctor before use if you have**

- Cough that occurs with too much phlegm (mucus)
- Cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema.
- Heart disease, high blood pressure, thyroid disease, or difficulty in urination due to enlargement of the prostate gland.
- The user has liver diseases
- The user is taking the blood thinning drug Warfarin

**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 exceed 6 doses in any 24-hour period.

AGE	DOSE
Adults and Children 12 years and over	10 ml (2 tsps) every 6 hours
Children 6 to under 12 years of age	5 ml (1 tsp) every 6 hours
Children under 6 years of age	Do not use

**Other Information:**

- Each 10 ml contains: sodium 4 mg
- Store between 15 - 30 degrees Celsius (59 - 86 Fahrenheit).
- Tamper Evident Feature: Do not use if seal under cap is torn, broken or missing.

**Inactive Ingredient**

Aloe Vera, Citric Acid, Disodium EDTA, FDC Red #40, Hydroxyethyl Cellulose, Natural Strawberry Flavor, Propylene Glycol USP, Purified Water, Sodium Benzoate, Sorbitol 70% USP, Sucralose.

**Questions or Comments**

Call Weekdays from 9:30 AM to 5PM EST at Tel 800-491-7908

Made in U.S.A.

**Drug Facts**

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**Novalgina**

**Children Cough & Cold**

• Cough  
• Fever Reducer  
• Pain Reliever  
• Cold

• Dextromethorphan Hydrobromide  
• Phenylephrine HCl  
• Acetaminophen  
• Guaifenesin

**6 oz. 180 mL**

**NON DROWSY · NO ALCOHOL · NO GLUTEN**

**Stop use and ask a doctor if**

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- Cough persists more than 1 week, tends to recur or is accompanied by a fever, rash or persistent headache. A persistent cough may be sign 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.

Avoid alcoholic beverages while you taking this product.

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Aloe Vera, Citric Acid, Disodium EDTA, FDC Red #40, Hydroxyethyl Cellulose, Natural Strawberry Flavor, Potassium Sorbate, Propylene Glycol USP, Purified Water, Sodium Benzoate, Sorbitol 70% USP, Sucralose.

**Questions or comments?**

Call Weekdays from 9:30 AM to 5 PM EST at Tel 305 2618762

Distributed by:

**LABOTICA** IMPORTS

6003 Bellaire Blvd., Houston, Tx, 77081

Lot # \_\_\_\_\_ Exp. Date: \_\_\_\_\_



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## NOVALGINA CHILDREN COUGH AND COLD

acetaminofen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83057-0001
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg in 10 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	13.33 mg in 10 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>HYDROXYETHYL CELLULOSE (100 MPAS AT 2%)</b> (UNII: R33S7TK2EP)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

<b>WATER</b> (UNII: 059QF0KOOR)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83057-0001-6	1 in 1 CARTON	11/01/2022	
1		180 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	11/01/2022	

### Labeler - HBC Pharma, LLC (063580631)

### Establishment

Name	Address	ID/FEI	Business Operations
GADAL Laboratories, Inc		841305639	manufacture(83057-0001)

Revised: 10/2023

HBC Pharma, LLC