

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

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 signserious condition.

Ask doctor before use if you have

- Cough that occurs with too much phlegm(mucus)
- Cough that last or is a chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema.
- Heart disease, high blood pressure, thyroid disease, or difficulty in urination due enlargement of prostate gland.
- The user has Liver diseases
- The user us 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 mls 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.

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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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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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Inactive ingredients	
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.



NOVALGINA CHILDREN COUGH AND COLD

acetaminofen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg in 10 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	13.33 mg in 10 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	

SUCRALOSE (UNII: 96K6UQ3ZD4)

ALOE VERA LEAF (UNII: ZY81Z83H0X)

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 Drug	M012	11/01/2022	

Labeler - HBC Pharma, LLC (063580631)

Establishment

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

Revised: 11/2024

HBC Pharma, LLC