NOVALGINA CHILDREN COUGH AND COLD- acetaminofen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid
All 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 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 og 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 contatins 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 no 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.

NOVALGINA CHILDREN COUGH AND COLD

acetaminofen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53149-2002
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**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53149-2002-6	1 in 1 CARTON	01/01/2015	
1		177 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	10/01/2001	

Labeler - All Pharma LLC (117605075)

Registrant - All Pharma LLC (117605075)

Establishment

Name	Address	ID/FEI	Business Operations
All Pharma LLC		117605075	MANUFACTURE(53149-2002)

Revised: 1/2020 All Pharma LLC