

**NOVALGINA ACETAMINOPHEN PAIN AND FEVER FOR CHILDRENS-  
acetaminophen 160mg suspension  
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 Acetaminophen Pain and Fever for Children's**

***Active Ingredient***

Acetaminophen, 160mg

***Purpose***

Pain reliever/fever reducer

***Uses***

temporarily:

■ reduces fever

■ relieves minor aches and pains due to: ■ the common cold ■ flu ■ headache ■ sore throat ■ toothache

***Warnings***

**Liver Warning:** This product contains acetaminophen. Severe liver damage may occur if your child takes ■ more than 5 doses in 24 hours, which is the maximum daily amount for this product

■ with other drugs containing acetaminophen.

**Allergy alert:** acetaminophen may cause severe skin reactions. Symptoms may include:

■ skin reddening ■ blisters ■ rash. If a skin reaction occurs, stop use and seek medical help right away

**Sore throat warning:** if sore throat is severe, persistent for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting. Consult a doctor promptly.

**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.
- If your child is allergic to acetaminophen or any of the inactive ingredients in this

product.

**Ask a doctor before use if your child**

has liver disease

**Ask a doctor or pharmacist before use if your**

child is taking the blood thinning drug warfarin

**Stop use and ask a doctor if**

■ pain gets worse or lasts more than 5 days ■ fever gets worse or lasts more than 3 days ■ new symptoms occur ■ redness or swelling is present. These could be signs of a serious condition.

**Keep out of reach of children.**

**Overdose warning** in case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222- 1222)

Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Overdose warning**

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222- 1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

Do not give more than directed, this product does not contain directions or complete warnings for adult use, find right dose on chart below. If possible, use weight to dose; otherwise, use age. Repeat dose every 4 hours while symptoms last, do not give more than 5 times in 24 hours. Attention use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

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<b>Weight (lbs)</b>	<b>Age (Years)</b>	<b>Dose</b>
under 24 lbs.	under 2 years	Ask a doctor
24-35 lbs.	2 - 3 years	5 mL
36-47 lbs.	4-5 years	7.5
48-59 lbs.	6-10 Years	10 mL
60-71 lbs	9-10 years	12.5 mL
72-95 lbs	11 years	15 ml

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**Other Information**

- Store between 20-25°C (68-77°F)
- Don't use if carton tape or bottle wrap imprinted with is broken or missing

### ***Inactive Ingredient***

Citric acid, corn syrup, FD&C red no. 40, glycerin, hydroxyethyl cellulose, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sorbitol solution, natural and artificial strawberry flavor, sucralose.

### ***Questions or Comments?***

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

### **Package**

### Drug Facts (continued)

Stop use and ask a doctor if pain gets worse or lasts more than 3 days, fever gets worse or lasts more than 3 days, new symptoms occur, redness or swelling is present. These could be signs of a serious condition.

Keep out of reach of children. Overdose vomiting is cause of overdose, get medical help or call a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions:** Do not give more than directed. This product does not contain dextrose or complete vitamins. For adult use, find right dose on chart below. If possible, use weight to dose. Otherwise, use age. Repeat dose every 4 hours while symptoms last, do not give more than 5 times in 24 hours. Administer use only measured dosing cup specifically designed for use with this product. Do not use any other dosing device.

Weight (lb)	Age (yr)	Dose (mL) *
under 25	under 2 years	ask a doctor
24-36	2-3 years	5 mL
36-47	4-5 years	7.5 mL
48-59	6-8 years	10 mL
60-71	9-10 years	12.5 mL
72-86	11 years	15 mL

**Other information:** Store between 20-25 °C (68-77°F) ■ Don't use if carton top or bottle is puffed, imprinted with broken or missing

**Inactive ingredients:** Citric acid, cumyl algin, FD&C red no. 40, glycerin, hydroxyethyl cellulose, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sodium sulfite, natural and artificial strawberry flavor, sucralose.

Questions or concerns? Call weekdays from 9:30 AM to 5 PM EST at Tel: 305 281 6782

# Novalgina

## ACETAMINOPHEN

# PAIN + FEVER

ORAL PAIN RELIEVER



6 FL OZ / 125 mL



Lot #  
Exp. Date

NDC: 1123-124-1251

### Drug Facts

Active Ingredient (in each 5 mL)	Purpose
Acetaminophen 160 mg	pain reliever, fever reducer

**Other important information:** **Acetaminophen** relieves minor aches and pains due to a flu, common cold or headache. It does not cure the cause.

**Warnings:** Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes more than 5 doses in 24 hours, which is the maximum daily amount with other drugs containing acetaminophen. Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include rash, redness, itching, hives, or blisters. If a skin reaction occurs, stop use and seek medical help right away. Some throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly. 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. If your child is allergic to acetaminophen or any of the inactive ingredients in this product, ask a doctor if your child has had a seizure. Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin. When using this product do not exceed recommended dose. Stop use and ask a doctor if pain gets worse or lasts more than 3 days, fever gets worse or lasts more than 3 days, new symptoms occur, redness or swelling is present. These could be signs of a serious condition.

**open here for continue Drug Facts ▼**



simulación  
de metalizado



# NOVALGINA ACETAMINOPHEN PAIN AND FEVER FOR CHILDRENS

acetaminophen 160mg suspension

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83057-0003
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL

**Inactive Ingredients**

Ingredient Name	Strength
CORN SYRUP (UNII: 9G5L16BK6N)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

**Product Characteristics**

Color		Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83057-0003-6	1 in 1 CARTON	07/15/2023	
1		125 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 not final	part343	06/08/2023	

**Labeler** - HBC Pharma, LLC (063580631)**Establishment**

Name	Address	ID/FEI	Business Operations
Gadal Laboratories, Inc		841305639	manufacture(83057-0003)

