

**CHILDRENS ACETAMINOPHEN- acetaminophen suspension  
ATLANTIC BIOLOGICALS CORP.**

*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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**Perrigo Children's Acetaminophen Drug Facts**

**Active ingredient (in each 5 mL)**

Acetaminophen 160 mg

**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
- 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, 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 has ever had an allergic reaction to this product or any of its ingredients

## 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

## When using this product

**do not exceed recommended dose (see overdose warning)**

## 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 even if you do not notice any signs or symptoms.

## Directions

- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed (see overdose warning)**
- **shake well before using**
- mL = milliliter
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- remove the child protective cap and squeeze your child's dose into the dosing cup
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (mL)*</b>
under 24	under 2 years	ask a doctor
24-35	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
72-95	11 years	15 mL

\*or as directed by a doctor

**Attention:** use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

### Other information

- **each 5 mL contains:** sodium 3 mg
- store at 20-25°C (68-77°F)
- **do not use if printed neckband is broken or missing**

### Inactive ingredients

anhydrous citric acid, butylparaben, calcium sulfate, carrageenan, D&C red #33, FD&C blue #1, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, tribasic sodium phosphate

### Questions or comments?

1-800-719-9260

### DISTRIBUTED BY:

ATLANTIC BIOLOGICALS CORP.

MIAMI, FL 33179

**Principal Display Panel Children's Acetaminophen Pain Reliever - Fever Reducer Oral Suspension For Ages 2 to 11 Years Aspirin Free Ibuprofen Free Alcohol Free Dosage Cup Included Grape Flavor**



**ACETAMINOPHEN  
ORAL SUSPENSION**

**160MG / 5ML**

**DELIVERS 80MG/ 2.5 mL Syringe**

**MFG: MEDTECH**

**MFG LOT# 0LK0592**

**EXP: 09/03/2021**

**UDS-MOR LOT# 369738**

**Dist. by: Atlantic Biologicals**



**17856020105**

**17856-0201-05**  
**Acetaminophen Oral**  
**Suspension**  
**80 mg / 2.5 mL**  
**Delivers 2.5 mL**



See package insert for indications and dosage schedule



Store at 20° to 25°C (68° to 77°F)  
Each 5 mL contains: sodium 3 mg. Aspirin/  
Ibuprofen/ Alcohol Free  
**KEEP OUT OF THE REACH OF CHILDREN**

**17856-0201-05**

**Dosage 2.5 mL**

**Acetaminophen Oral**  
**Suspension**

**Qty: 60 Enfit Syringes**



**GTIN: 00117856020158**

**S/N: 01545702**

**Exp: 04/01/22**

**Lot: 015457**



Packaged by: Unit Dose Solutions  
Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp.  
Miami FL 33179

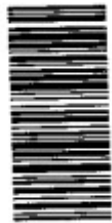
Rev 08/21

**Call to Reorder: 800.509.7592**

**17856-0201-03**  
**Acetaminophen Oral**  
**Suspension**  
**160 mg / 5 mL**  
**Delivers 5 mL**



See package insert for indications and dosage schedule



Store at 20° to 25°C (68° to 77°F)  
Each 5 mL contains: sodium 3 mg. Aspirin/  
Ibuprofen/ Alcohol Free  
**KEEP OUT OF THE REACH OF CHILDREN**

**17856-0201-03**

**Dosage 160 MG / 5 ML**

**Acetaminophen Oral**  
**Suspension**

**Qty: 48 Syringes**



**GTIN: 00117856020134**

**S/N: 01545801**

**Exp: 04/01/22**

**Lot: 015458**



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Rev 08/21

**Call to Reorder: 800.509.7592**

**17856-0201-09**  
**Acetaminophen Oral**  
**Suspension**  
**80 mg / 2.5 mL**  
**Delivers 2.5 mL**



See package insert for indications and dosage schedule

Store at 20° to 25°C (68° to 77°F)  
Each 5 mL contains: sodium 3 mg. Aspirin/  
Ibuprofen/ Alcohol Free  
**KEEP OUT OF THE REACH OF CHILDREN**



**17856-0201-09**

**Dosage 2.5 mL**

**Acetaminophen Oral**  
**Suspension**

Qty: **120 Enfit**  
**Syringes**



**GTIN: 00117856020196**

**S/N: 01545501**

**Exp: 03/30/22**

**Lot: 015455**



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Rev.08/21

**Call to Reorder: 800.509.7592**

**17856-0201-06**  
Acetaminophen Oral  
Suspension  
240 mg / 7.5 mL  
Delivers 7.5 mL



See package insert for indications and dosage schedule



Store at 20° to 25°C (68° to 77°F)  
Each 5 mL contains: sodium 3 mg. Aspirin/  
Ibuprofen/ Alcohol Free  
**KEEP OUT OF THE REACH OF CHILDREN**

**17856-0201-06**

**Dosage 240 MG/ 7.5 ML**

**Acetaminophen Oral  
Suspension**

Qty: **48 ENFit  
Syringes**



**GTIN: 00117856020165**

**S/N: 01546001**

**Exp: 04/01/22**

**Lot: 015460**



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Miami FL 33179

Rev.08/21

**Call to Reorder: 800.509.7592**



**17856-0201-04**  
Acetaminophen Oral  
Suspension  
160 mg / 5 mL  
Delivers 5 mL



See package insert for indications and dosage schedule

Store at 20° to 25°C (68° to 77°F)  
Each 5 mL contains: sodium 3 mg. Aspirin/  
Ibuprofen/ Alcohol Free  
**KEEP OUT OF THE REACH OF CHILDREN**



**17856-0201-04**                      **Dosage 160 MG / 5 ML**  
**Acetaminophen Oral**  
**Suspension**                              **Qty: 72 CUPS**



GTIN: 00117856020141  
S/N: 01545901  
Exp: 04/01/22  
Lot: 015459



Packaged by: Unit Dose Solutions  
Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp,  
Miami FL 33179

Rev 08/21

**Call to Reorder: 800.509.7592**

**CUT ME OFF**



LOT#: 373369    DIST. BY: GNP LOT#: DMK0813

PKG BY: UDS MOR    ALCOHOL & ASPIRIN & IBUPROFEN FREE

DIST BY: ATLANTIC BIOLOGICALS    EXPIRATION: 02/28/2022

**CHILDREN'S PAIN & FEVER (Acetaminophen)**  
**DELIVERS 240MG/7.5ML ORAL SYRINGE**  
**FEVER REDUCER & PAIN RELIEVER**  
**GRAPE FLAVORED**

**CHILDRENS ACETAMINOPHEN**

acetaminophen suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:17856-0201(NDC:45802-201)
<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	160 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>BUTYLPARABEN</b> (UNII: 3QPI1U3FV8)	
<b>CALCIUM SULFATE</b> (UNII: WAT0DDB505)	
<b>CARRAGEENAN</b> (UNII: 5C69YCD2YJ)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SODIUM PHOSPHATE, TRIBASIC</b> (UNII: A752Q30A6X)	

### Product Characteristics

<b>Color</b>	PURPLE (viscous)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-0201-1	120 in 1 BOX, UNIT-DOSE	10/11/2021	
1		2.5 mL in 1 SYRINGE; Type 0: Not a Combination Product		
2	NDC:17856-0201-2	120 in 1 BOX, UNIT-DOSE	10/11/2021	
2		1.25 mL in 1 SYRINGE; Type 0: Not a Combination Product		

3	NDC:17856-0201-3	48 in 1 BOX, UNIT-DOSE	10/11/2021	
3		5 mL in 1 SYRINGE; Type 0: Not a Combination Product		
4	NDC:17856-0201-4	72 in 1 BOX, UNIT-DOSE	10/28/2021	
4		5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
5	NDC:17856-0201-5	60 in 1 BOX, UNIT-DOSE	10/11/2021	
5		2.5 mL in 1 SYRINGE; Type 0: Not a Combination Product		
6	NDC:17856-0201-6	48 in 1 BOX, UNIT-DOSE	10/11/2021	
6		7.5 mL in 1 SYRINGE; Type 0: Not a Combination Product		
7	NDC:17856-0201-7	72 in 1 BOX, UNIT-DOSE	10/11/2021	
7		15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
8	NDC:17856-0201-8	120 in 1 BOX, UNIT-DOSE	10/11/2021	
8		2 mL in 1 SYRINGE; Type 0: Not a Combination Product		
9	NDC:17856-0201-9	120 in 1 BOX, UNIT-DOSE	10/11/2021	
9		2.5 mL in 1 SYRINGE; 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	04/09/2014	

**Labeler** - ATLANTIC BIOLOGICALS CORP. (047437707)

## Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	relabel(17856-0201) , repack(17856-0201)

Revised: 10/2021

ATLANTIC BIOLOGICALS CORP.