GOOD NEIGHBOR PHARMACY CHILDRENS PAIN AND FEVER-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.

Amerisource Bergen Children's Pain & Fever 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

Weight (lb)	Age (yr)	Dose (mL)*
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?

DISTRIBUTED BY:

ATLANTIC BIOLOGICALS CORP.

20101 N.E 16TH PLACE

MIAMI, FL 33179

Compare to Children's Tylenol® Oral Suspension active ingredient

FOR AGES 2 TO 11 YEARS

children's

Pain & Fever

acetaminophen 160 mg per 5 mL

oral suspension

Fever Reducer – Pain Reliever

Aspirin Free

Ibuprofen Free

Alcohol Free

Grape Flavor

17856-0209-02



ACETAMINOPHEN (PAIN & FEVER) ORAL SUSPENSION 64 MG/2 ML

See package insert for indications and dosage schedule

Store at 20-25°C (68-77°F). FEVER REDUCER-PAIN RELIEVER ASPIRIN FREE-IBUPROFEN FREE-ALCOHOL FREE

**** Keep this and all Medication out of the reach of children

17856-0209-02 PAIN & FEVER Dosage: 2 mL Syr

Qty: 120 Syringes

GTIN: 1785602092 S/N: 000000000000002

Exp: 11/22/19

Lot: 000000

17856020902

Packaged by: Unit Dose Solutions

OTC

Morrisville, NC 27560

Distributed by: AtlanticBiologicals

Corp, Miami FI 33179



ACETAMINOPHEN (PAIN & FEVER) ORAL SUSPENSION 120 MG/3.75 ML

Rev.01/19

See package insert for indications and dosage schedule

Store at 20-25°C (68-77°F). FEVER REDUCER-PAIN RELIEVER ASPIRIN FREE-IBUPROFEN FREE-ALCOHOL FREE

**** Keep this and all Medication out of the reach of children

17856-0209-04

Dosage: 3.75mL Syr

PAIN & FEVER

Qty: 120 Syringes

GTIN: 1785602094

S/N: 00000000000004

Exp: 11/22/19 Lot: 000000



17856020904

Packaged by: Unit Dose Solutions

OTC

Morrisville, NC 27560

Distributed by: AtlanticBiologicals

Corp, Miami FI 33179



ACETAMINOPHEN (PAIN & FEVER) ORAL SUSPENSION 192 MG/6 ML

See package insert for indications and dosage schedule

Store at 20-25°C (68-77°F), FEVER REDUCER-PAIN RELIEVER ASPIRIN FREE-IBUPROFEN FREE-ALCOHOL

** Keep this and all Medication out of the reach of children

17856-0209-06 PAIN & FEVER

Dosage: 6 mL Syr

Qty: 48 Syringes

GTIN: 1785602096

S/N: 00000000000006

Exp: 11/22/19 Lot: 000000

17856020906

Packaged by: Unit Dose Solutions

OTC

Morrisville, NC 27560

Distributed by: AtlanticBiologicals

Corp, Miami FI 33179

17856-0209-08



ACETAMINOPHEN (PAIN & FEVER) ORAL SUSPENSION 325 MG/10.15 ML

See package insert for indications and dosage schedule

Store at 20-25°C (68-77°F). FEVER REDUCER-PAIN RELIEVER ASPIRIN FREE-IBUPROFEN FREE-ALCOHOL FREE

**** Keep this and all Medication out of the reach of children

17856-0209-08 PAIN & FEVER Dosage: 10.15 mL

AIN OF LAFE

Qty: 72 Cups

GTIN: 1785602098

S/N: 000000000000008

Exp: 11/22/19 Lot: 000000

Exp: 11/22/19

Lot: 000000

Pac

Packaged by: Unit Dose Solutions

OTC

Morrisville, NC 27560

17856020908 Distributed by: AtlanticBiologicals

Corp, Miami FI 33179

ACETAMINOPHEN (PAIN & FEVER) ORAL SUSPENSION 48 MG/1.5ML

Rev.01/19

See package insert for indications and dosage schedule

Store at 20-25°C (68-77°F). FEVER REDUCER-PAIN RELIEVER ASPIRIN FREE-IBUPROFEN FREE-ALCOHOL FREE

**** Keep this and all Medication out of the reach of children

17856-0209-01 PAIN & FEVER Dosage: 1.5mL Syr

Qty: 120 Syringes

GTIN: 1785602091 S/N: 000000000000001

Exp: 11/22/19

OTC

Lot: 000000

17856020001

17856020901

Packaged by: Unit Dose Solutions

Morrisville, NC 27560

Distributed by: AtlanticBiologicals

Corp, Miami FI 33179

Call to Reorder: 800.509.7592

GOOD NEIGHBOR PHARMACY CHILDRENS PAIN AND FEVER

acetaminophen suspension

Product Information	
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:17856-0209(NDC:46122-211)

Route of Administration ORAL

Active	Ingredient	:/Active	Moiety
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Ingredient Name	Basis of Strength	Strength
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	160 mg in 5 mL

Inactive 1	Ingre	dients
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Ingredient Name Strength

ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CALCIUM SULFATE (UNII: WAT0 DDB 50 5)	
CARRAGEENAN (UNII: 5C69 YCD2YJ)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTO SE CORN SYRUP (UNII: XY6 UN3QB6S)	
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SODIUM PHO SPHATE, TRIBASIC (UNII: A752Q30A6X)	

Color PURPLE ((viscous)	Score	
Chana		Score	
Shape		Size	
Flavor GRAPE		Imprint Code	
Contains			

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#	Item Code	Package Description	Marketing Start	Marketing End
#	Item Code	rackage Description	Date	Date
1	NDC:17856-0209-	120 in 1 BOX, UNIT-DOSE	01/18/2021	
1		1.5 mL in 1 SYRINGE; Type 0: Not a Combination Product		
2	NDC:17856-0209- 2	120 in 1 BOX, UNIT-DOSE	01/18/2021	
2		2 mL in 1 SYRINGE; Type 0: Not a Combination Product		
3	NDC:17856-0209-	120 in 1 BOX, UNIT-DOSE	01/18/2021	
3		3 mL in 1 SYRINGE; Type 0: Not a Combination Product		
4	NDC:17856-0209-	120 in 1 BOX, UNIT-DOSE	01/18/2021	
4		3.75 mL in 1 SYRINGE; Type 0: Not a Combination Product		
5	NDC:17856-0209- 5	72 in 1 BOX, UNIT-DOSE	01/18/2021	
5		5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
6	NDC:17856-0209-	48 in 1 BOX, UNIT-DOSE	01/18/2021	
6		6 mL in 1 SYRINGE; Type 0: Not a Combination Product		
7	NDC:17856-0209-	48 in 1 BOX, UNIT-DOSE	01/18/2021	
7		7.5 mL in 1 SYRINGE; Type 0: Not a Combination Product		
8	NDC:17856-0209-	72 in 1 BOX, UNIT-DOSE	01/18/2021	
8		10.15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

9 NDC:17856-0209-	50 in 1 BOX, UNIT-DOSE	01/18/2021	
9	15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
Marketing In	formation		
Marketing In		Marketing Start Date	Marketing End Date
	ory Application Number or Monograph Citation	Marketing Start Date 05/22/2019	Marketing End Date

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment			
Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	relabel(17856-0209), repack(17856-0209)

Revised: 1/2021 ATLANTIC BIOLOGICALS CORP.