

ACETAMINOPHEN- acetaminophen elixir
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.

Children's Pain Relief
Grape Flavor
Pain Reliever and Fever Reducer

Active ingredient (in each 5 mL = 1 teaspoonful)

Acetaminophen 160 mg

Purpose

Pain Reliever/Fever Reducer

Uses

To reduce fever and for the temporary relief of minor aches and pains due to:

- headache
- muscular aches
- backache
- minor pain of arthritis
- the common cold
- toothache
- premenstrual and menstrual cramps.

Temporarily reduces fever.

Warnings

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, which is the maximum daily amount taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks everyday while using this product.

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 non-prescription). 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
- is on a sodium-restricted diet.

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 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.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose Warning:

taking more than the recommended dose (overdose) may cause liver damage.

In case of overdose get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults/children even if you do not notice any signs or symptoms.

Directions

- shake well before using
- find the right dose on chart below, if possible, use weight to dose; otherwise use age
- dosage may be repeated every 4 hours, or as directed by your doctor
- do not use more than 5 doses in 24 hours
- do not use more than 5 days unless directed by a doctor.
- find right dose on chart below, If possible, use weight to dose; otherwise, use age.

Weight (lbs.)	Age (years)	dosage-teaspoonful (tsp.)
under 24	under 2	consult Physician
24 to 35	2 to 3	1 tsp. (5 mL)
36 to 47	4 to 5	1 1/2 tsp. (7.5 mL)
48 to 59	6 to 8	2 tsp. (10 mL)
60 to 71	9 to 10	2 1/2 tsp. (12.5 mL)
72 to 95	11	3 tsp. (15 mL)

Other information

- Store at room temperature 15°-30° C (59°-86°F)
- Protect from Freezing.
- Protect from Light.

TAMPER EVIDENT: DO NOT USE IF BREAKAWAY BAND ON CAP IS BROKEN OR MISSING.

Inactive Ingredients:

Grape Flavor, Citric Acid, Glycerin, Polyethylene Glycol 400, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol Solution 70% & Sodium Benzoate.

How Supplied:

17856-5401-01 ACETAMINOPHEN - 48MG/1.5ML SYRINGE 120 UD
17856-5401-02 ACETAMINOPHEN - 64MG/2ML SYRINGE 120 UD
17856-5401-03 ACETAMINOPHEN - 96MG/3ML SYIRNGE 120 UD
17856-5401-04 ACETAMINOPHEN - 3.75 ML SYRINGE 48 ct UD
17856-5401-05 ACETAMINOPHEN - 5 ML CUP 72 ct UD
17856-5401-06 ACETAMINOPHEN - 192MG/6ML SYRINGE 48 ct UD
17856-5401-07 ACETAMINOPHEN - 240MG/7.5ML SYRINGE 48 ct UD
17856-5401-08 ACETAMINOPHEN - 325MG/10.15 ML CUP 72 ct UD
17856-5401-09 ACETAMINOPHEN - 480MG/15ML 50 CUP ct UD

Questions or Comments?

Call (877) 225-6999 Monday - Friday 9AM-5PM EST

**Manufactured for
Akron Pharma, Inc.,
Fairfield, NJ - 07004**

Manufactured In USA

* This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol Elixir

Distributed by:

ATLANTIC BIOLOGICALS CORP.

Miami, FL 33179

Principal Display Panel

• Compare To Active ingredient of Children's Tylenol Elixir

Children's

Pain Relief

**Pain Reliever and
Fever Reducer**

Acetaminophen 160 mg per 5 ml Oral Elixir

• Alcohol Free

- *Asprin Free*
 - *For Ages 2 - 11 years*
- Grape Flavor**

17856-5401-01
CHILDREN'S PAIN RELIEF
(ACETAMINOPHEN)
ORAL ELIXIR
48 MG/ 1.5 ML
DELIVERS 1.5 ML



See package insert for indications and dosage schedule

Store at room temperature 15°-30°C
(59°-86°F). Protect from light and freezing. Pain
Reliever / Fever Reducer
Alcohol & Aspirin Free, Grape Flavor
**KEEP THIS AND ALL MEDICATION OUT OF
THE REACH OF CHILDREN**



17856-5401-01 Dosage: 48 MG/ 1.5 ML

CHILDREN'S PAIN RELIEF
(ACETAMINOPHEN) Qty: 120 Syringes



GTIN: 00117856540113
S/N: 01142201
Exp: 02/25/21
Lot: 011422

OTC

Packaged by: Unit Dose Solutions
Morrisville, NC 27560

Distributed by: AtlanticBiologicals Corp.
Miami FL 33179

Rev. 09/19

Call to Reorder: 800.509.7592

17856-5401-02
CHILDREN'S PAIN RELIEF
(ACETAMINOPHEN)
ORAL ELIXIR
64 MG/ 2 ML
DELIVERS 2 ML



See package insert for indications and dosage schedule.

Store at room temperature 15°-30°C
(59°-86°F). Protect from light and freezing. Pain
Reliever / Fever Reducer
Alcohol & Aspirin Free. Grape Flavor
**KEEP THIS AND ALL MEDICATION OUT OF
THE REACH OF CHILDREN**



17856540102

17856-5401-02

Dosage: 64 MG /2 ML

CHILDREN'S PAIN RELIEF
(ACETAMINOPHEN)

Qty: 120 Syringes



GTIN: 00117856540120

S/N: 01142301

Exp: 02/25/21

Lot: 011423

OTC

Packaged by Unit Dose Solutions
Morrisville, NC 27560

Distributed by: AtlanticBiologicals Corp.
Miami FL 33179

Rev. 09/19

Call to Reorder: 800.509.7592

17856-5401-05

CHILDREN'S PAIN RELIEF . LOOSE
(ACETAMINOPHEN)

ORAL ELIXIR

160 MG/ 5 ML

DELIVERS 5 ML

See package insert for indications and dosage schedule

Store at room temperature 15°-30°C
(59°-86°F). Protect from light and freezing. Pain
Reliever / Fever Reducer
Alcohol & Aspirin Free. Grape Flavor
**KEEP THIS AND ALL MEDICATION OUT OF
THE REACH OF CHILDREN**



17856-5401-05

Dosage: 160 MG / 5 ML

**CHILDREN'S PAIN RELIEF
(ACETAMINOPHEN)**

Qty: 72 CUPS



GTIN: 00117856540151

S/N: 01142801

Exp: 02/25/21

Lot: 011428

OTC

Packaged by Unit Dose Solutions
Morrisville, NC 27560

Distributed by: AtlanticBiologicals Corp,
Miami FL 33170

Rev. 09.19

Call to Reorder: 800.509.7592

17856-5401-06
CHILDREN'S PAIN RELIEF
(ACETAMINOPHEN)
ORAL ELIXIR
192 MG/ 6 ML
DELIVERS 6 ML



See package insert for indications and dosage schedule

Store at room temperature 15°-30°C
(59°-86°F). Protect from light and freezing. Pain
Reliever / Fever Reducer
Alcohol & Aspirin Free. Grape Flavor
**KEEP THIS AND ALL MEDICATION OUT OF
THE REACH OF CHILDREN**



17856-5401-06

Dosage: 192 MG/ 6ML

CHILDREN'S PAIN RELIEF
(ACETAMINOPHEN)

Qty: 48 Syringes



GTIN: 00117856540168

S/N: 01143001

Exp: 02/25/21

Lot 011430

OTC

Packaged by Unit Dose Solutions
Merricville, NC 27560

Distributed by: AtlanticBiologics Corp.
Miami, FL 33179

Rev. 09.19

Call to Reorder: 800.509.7592

17856-5401-09
CHILDREN'S PAIN RELIEF
(ACETAMINOPHEN)
ORAL ELIXIR
480 MG/ 15 ML
DELIVERS 15 ML



See package insert for indications and dosage schedule

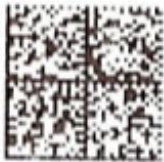
Store at room temperature 15°-30°C
(59°-86°F). Protect from light and freezing. Pain
Reliever / Fever Reducer
Alcohol & Aspirin Free. Grape Flavor
**KEEP THIS AND ALL MEDICATION OUT OF
THE REACH OF CHILDREN**



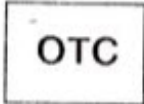
17856540109

17856-5401-09 **Dosage: 480 MG/15ML**

CHILDREN'S PAIN RELIEF
(ACETAMINOPHEN) **Qty: 50 CUPS**



GTIN: 00117856540199
S/N: 01143401
Exp: 02/25/21
Lot: 011434



Packaged by Unit Dose Solutions
Morrisville, NC 27560

Distributed by: AtlanticBiologicals Corp.
Miami FL 33179

Rev. 09/19

Call to Reorder: 800.509.7592

**CHILDREN'S PAIN RELIEF
(ACETAMINOPHEN)
480 MG/15 ML
ORAL ELIXIR
DELIVERS 15 ML**



17856540109

**DISTRIBUTED BY ATLANTIC
BIOLOGICALS CORP.**

Exp:08/26/2020

Lot#lot1

Mfg:FOR: AKRON Mfg Lot #XXXX

Pkg by UDS

Morrisville, NC 27560

**CHILDREN'S PAIN RELIEF
(ACETAMINOPHEN)
160 MG/5 ML
ORAL ELIXIR
DELIVERS 5 ML**



17856540105

**DISTRIBUTED BY ATLANTIC
BIOLOGICALS CORP.**

Exp:08/26/2020

Lot#lot1

Mfg:FOR: AKRON Mfg Lot #XXXX

Pkg by UDS

Morrisville, NC 27560

ACETAMINOPHEN

acetaminophen elixir

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-5401(NDC:71399-0161)
Route of Administration	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
GRAPE (UNII: 6X543N684K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-5401-1	120 in 1 BOX, UNIT-DOSE	09/02/2020	
1		1.5 mL in 1 SYRINGE; Type 0: Not a Combination Product		
2	NDC:17856-5401-2	120 in 1 BOX, UNIT-DOSE	09/02/2020	
2		2 mL in 1 SYRINGE; Type 0: Not a Combination Product		
3	NDC:17856-5401-3	120 in 1 BOX, UNIT-DOSE	09/02/2020	
3		3 mL in 1 SYRINGE; Type 0: Not a Combination Product		
4	NDC:17856-5401-4	48 in 1 BOX, UNIT-DOSE	09/02/2020	
4		3.75 mL in 1 SYRINGE; Type 0: Not a Combination Product		
5	NDC:17856-5401-5	72 in 1 BOX, UNIT-DOSE	09/02/2020	
5		5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
6	NDC:17856-5401-6	48 in 1 BOX, UNIT-DOSE	09/02/2020	
6		6 mL in 1 SYRINGE; Type 0: Not a Combination Product		
7	NDC:17856-5401-7	48 in 1 BOX, UNIT-DOSE	09/02/2020	
7		7.5 mL in 1 SYRINGE; Type 0: Not a Combination Product		
8	NDC:17856-5401-8	72 in 1 BOX, UNIT-DOSE	09/02/2020	
8		10.15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
9	NDC:17856-5401-9	50 in 1 BOX, UNIT-DOSE	09/02/2020	
9		15 mL in 1 CUP, UNIT-DOSE; 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	07/28/2020	

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

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	relabel(17856-5401) , repack(17856-5401)

