

**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.*

-----  
**Acetaminophen Elixir**

**Bubble Gum Flavor**

**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.

---

<b>Weight (lbs.)</b>	<b>Age (years)</b>	<b>dosage-teaspoonful (tsp.)</b>
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:**

Bubble Gum Flavor, Citric Acid, FD C RED #40, Glycerin, Polyethylene Glycol 400, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol Solution 70% & Sodium Benzoate.

**Questions or Comments?**

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

**DISTRIBUTED BY:**

**ATLANTIC BIOLOGICALS CORP.**

**MIAMI, FL 33179**

**17856-0175-01**  
**CHILDREN'S PAIN RELIEF**  
**(ACETAMINOPHEN)**  
**ORAL ELIXIR**  
**80MG /2.5 ML**  
**DELIVERS 2.5ML**



See package insert for indications and dosage schedule

Store at room temperature 15°-30° C (59°-86°F)  
Protect from light. Protect from freezing. Pain  
Reliever and Fever Reducer  
Alcohol & Aspirin Free  
**\*\* Keep this and all medication out of the reach  
of children\*\***



17856017501

**17856-0175-01**

**Dosage 80 MG / 2.5 ML**

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

Qty: **60 ENFit**  
**SYRINGES**



**GTIN: 00117856017516**

**S/N: 01874001**

**Exp: 04/21/23**

**Lot: 018740**



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**

**17856-0175-04**  
**CHILDREN'S PAIN RELIEF**  
**(ACETAMINOPHEN)**  
**ORAL ELIXIR**  
**80MG /2.5 ML**  
**DELIVERS 2.5ML**



See package insert for indications and dosage schedule

Store at room temperature 15°-30° C (59°-86°F)  
Protect from light. Protect from freezing. Pain  
Reliever and Fever Reducer  
Alcohol & Aspirin Free  
\*\* Keep this and all medication out of the reach  
of children\*\*



**17856-0175-04**

**Dosage 80 MG / 2.5 ML**

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

Qty: **120 ENFit**  
**SYRINGES**

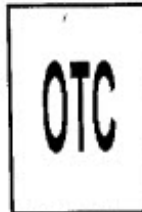


**GTIN: 00117856017547**

**S/N: 01873401**

**Exp: 04/21/23**

**Lot: 018734**



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**

**17856-0175-07**  
**CHILDREN'S PAIN RELIEF**  
**(ACETAMINOPHEN)**  
**ORAL ELIXIR**  
**80MG /2.5 ML**  
**DELIVERS 2.5ML**



See package insert for indications and dosage schedule

Store at room temperature 15°-30° C (59°-86°F)  
 Protect from light. Protect from freezing. Pain  
 Reliever and Fever Reducer  
 Alcohol & Aspirin Free  
 \*\* Keep this and all medication out of the reach  
 of children\*\*



**17856-0175-07**

**Dosage 80MG/2.5 ML**

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

**Qty: 120 SYRINGES**



**GTIN: 00117856017578**

**S/N: 01873901**

**Exp: 04/21/23**

**Lot: 018739**



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**

**ACETAMINOPHEN**

acetaminophen elixir

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:17856-0175(NDC:71399-0160)
<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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

### Product Characteristics

Color		Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-0175-3	5 in 1 SYRINGE	10/25/2022	
1	NDC:17856-0175-1	60 in 1 BOX, UNIT-DOSE		
1	NDC:17856-0175-2	2.5 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:17856-0175-6	5 in 1 SYRINGE	10/25/2022	
2	NDC:17856-0175-4	120 in 1 BOX, UNIT-DOSE		
2	NDC:17856-0175-5	2.5 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:17856-0175-9	5 in 1 SYRINGE	10/25/2022	
3	NDC:17856-0175-7	120 in 1 BOX, UNIT-DOSE		
3	NDC:17856-0175-8	2.5 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	05/18/2021	

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

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
UNIT DOSE SOLUTIONS		360804194	repack(17856-0175)

Revised: 11/2022

ATLANTIC BIOLOGICALS CORP.