

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)

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 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

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.

Keep out of reach of children.

Overdose Warning:

In case of overdose get medical help or contact a Poison Control Center (1-800-222-1222) right away. 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**
- **shake well before using**
- **mL=milliliter**
- find the right dose on chart below, if possible, use weight to dose; otherwise use age
- use only the enclosed dosing cup designed for use with this product.
- Do not use any other dosing device.
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give more than 5 days unless directed by doctor.

Weight (lbs.)

Age (years)

dosage-teaspoonful (tsp.)

under 24	under 2	ask a doctor
24 to 35	2 to 3	1 tsp or 5 mL
36 to 47	4 to 5	1 1/2 tsp or 7.5 mL
48 to 59	6 to 8	2 tsp or 10 mL
60 to 71	9 to 10	2 1/2 tsp or 12.5 mL
72 to 95	11	3 tsp or 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, glycerin, polyethylene glycol 400, purified water, sodium citrate, saccharin sodium, sorbitol solution & sodium benzoate.

Questions or Comments?

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

DISTRIBUTED BY:

ATLANTIC BIOLOGICALS CORP.

MIAMI, FL 33179

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

17856-0166-01

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

ORAL ELIXIR

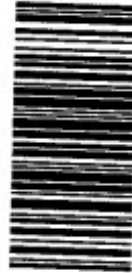
325MG /10.15 ML

DELIVERS 10.15ML

 **UDOSE**

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**



17856016601

17856-0166-01

Dosage 325 MG / 10.15 ML

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

Qty: 72 CUPS



GTIN: 00117856016618

S/N: 01874101

Exp: 04/21/23

Lot: 018741



Packaged by: Unit Dose Solutions
Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp,
Miami FL 33179

Rev.08/21

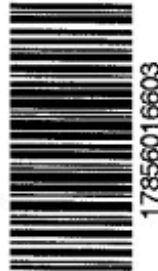
Call to Reorder: 800.509.7592

17856-0166-03
CHILDREN'S PAIN RELIEF
(ACETAMINOPHEN)
ORAL ELIXIR
650 MG /20.31 ML
DELIVERS 20.31 ML



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**



17856-0166-03 **Dosage 650 MG /20.31 ML**

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



GTIN: 00117856016632
S/N: 01872501
Exp: 04/20/23
Lot: 018725



Packaged by: Unit Dose Solutions
Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp
Miami FL 33179

Rev.08/21

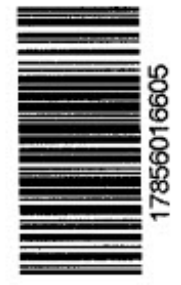
Call to Reorder: 800.509.7592

17856-0166-05
CHILDREN'S PAIN RELIEF
(ACETAMINOPHEN)
ORAL ELIXIR
480 MG /15 ML
DELIVERS 15ML



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**



17856-0166-05 **Dosage 480 MG /15 ML**
CHILDREN'S PAIN RELIEF **Qty: 72 CUPS**
(ACETAMINOPHEN)



GTIN: 00117856016656
S/N: 01871601
Exp: 04/20/23
Lot: 018716



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			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-0166(NDC:71399-0160)
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
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:17856-0166-1	72 in 1 BOX, UNIT-DOSE	03/13/2023	
1	NDC:17856-0166-2	10.15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:17856-0166-3	50 in 1 BOX, UNIT-DOSE	03/13/2023	
2	NDC:17856-0166-4	20.31 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
3	NDC:17856-0166-7	50 in 1 BOX, UNIT-DOSE	03/13/2023	
3	NDC:17856-0166-8	31.2 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
4	NDC:17856-0166-5	72 in 1 BOX, UNIT-DOSE	03/13/2023	
4	NDC:17856-0166-6	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	05/18/2021	

Labeler - ATLANTIC BIOLOGICALS CORP (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
UNIT DOSE SOLUTIONS		360804194	repack(17856-0166)

Revised: 3/2023

ATLANTIC BIOLOGICALS CORP