

**CHILDRENS SILAPAP- acetaminophen liquid**  
**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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**Children's Silapap Liquid**

Active Ingredient: Acetaminophen 160 mg (in each 5 mL (TSP))

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

**Warnings**

**Liver Warning:**This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day 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.

**Alcohol warning:**if the user consumes 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers.

**Do not use**

- with any other product drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if the user is allergic to acetaminophen or any of the inactive ingredients in this product

**When using this product**

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

**Stop use and ask a doctor if**

- **new symptoms occur**
- redness or swelling is present
- pain gets worse or lasts for more than 5 days
- fever gets worse or lasts for more than 3 days
- 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:** In case of overdose, get medical help or contact a Poison Control Center (1800-222-1222) right away. Quick medical attention is critical even if you do not notice any signs of symptoms.

**Directions**

- do not take more than directed (see overdose warning).
- if needed, repeat dose every 4 hours or as directed by a doctor
- do not give more than 5 doses in 24 hours

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children under 2 yrs (under 24 lbs)	ask a doctor
children 2-3 years (24-35 lbs)	1 teaspoonful (TSP)(5 mL)
children 4-5 years (36-47 lbs)	1 1/2 teaspoonfuls (TSP)(7.5 mL)
children 6-8 years (48-59 lbs)	2 teaspoonfuls (TSP)(10 mL)
children 9-10 years (60-71 lbs)	2 1/2 teaspoonfuls (TSP)(12.5 mL)
children 11 years (72-95 lbs)	3 teaspoonfuls (TSP)(15 mL)
adults & children 12 years & older	4 teaspoonfuls (TSP)(20 mL)

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**Other information**

Store at room temperature 20°-25°C (68°-77°F)

**Inactive ingredients**

citric acid, D&C red no. 33, FD&C red no. 40, cherry flavor, methylparaben, propylene glycol, saccharin sodium, sodium benzoate, and purified water.

**Questions****DISTRIBUTED BY:**

ATLANTIC BIOLOGICALS CORP.

20101 NE 16TH PLACE

MIAMI, FL 33179

**ACETAMINOPHEN (SILAPAP)**

17856-0141-01



ACETAMINOPHEN (SILAPAP)  
650 MG/20.31 ML ORAL LIQUID

Rev.01/19

See package insert for indications and dosage schedule

Store at room temperature 20°-25° (68°-77° F) PAIN  
RELIEVER, FEVER REDUCER  
ALCOHOL FREE-ASPIRIN FREE-SUGAR FREE  
KEEP OUT OF THE REACH OF CHILDREN

17856-0141-01  
SILAPAP

Dosage: 20.31 ML

Qty: 50 Cups



GTIN: 1785601411  
S/N: 00000000000002  
Exp: 10/03/20  
Lot: 000000



17856014101

Packaged by: Unit Dose Solutions  
Morrisville, NC 27560

Distributed by: AtlanticBiologicals  
Corp, Miami FL 33179

Call to Reorder: 800.509.7592

17856-0141-02



**ACETAMINOPHEN (SILAPAP)  
1000 MG/31.25 ML ORAL LIQUID**

Rev.01/19

See package insert for indications and dosage schedule

Store at room temperature 20°-25°(68°-77°F) PAIN  
RELIEVER, FEVER REDUCER  
ALCOHOL FREE-ASPIRIN FREE-SUGAR FREE  
KEEP OUT OF THE REACH OF CHILDREN

17856-0141-02  
SILAPAP

Dosage: 31.25 ML

Qty: 50 Cups



GTIN: 1785601412  
S/N: 00000000000003  
Exp: 10/03/20  
Lot: 000000

OTC



17856014102

Packaged by: Unit Dose Solution  
Morrisville, NC 27560

Distributed by: AtlanticBiologica  
Corp, Miami FL 33179

Call to Reorder: 800.509.7592

17856-0141-04



ACETAMINOPHEN (SILAPAP) 80  
MG/2.5 ML ORAL LIQUID

Rev.01/19

See package insert for indications and dosage schedule

Store at room temperature 20°-25° (68°-77°F) PAIN  
RELIEVER, FEVER REDUCER  
ALCOHOL FREE-ASPIRIN FREE-SUGAR FREE  
KEEP OUT OF THE REACH OF CHILDREN

17856-0141-04  
SILAPAP

Dosage: 2.5 ML SYR

Qty: 120 Syringes



GTIN: 1785601414  
S/N: 00000000000007  
Exp: 10/03/19  
Lot: 000000

OTC



17856014104

Packaged by: Unit Dose Solution  
Morrisville, NC 27560

Distributed by: AtlanticBiologica  
Corp, Miami FL 33179

Call to Reorder: 800.509.7592



17856-0141-05



ACETAMINOPHEN (SILAPAP)  
160 MG/5 ML ORAL LIQUID

Rev.01/19

See package insert for indications and dosage schedule

Store at room temperature 20°-25° (68°-77° F) PAIN  
RELIEVER, FEVER REDUCER  
ALCOHOL FREE-ASPIRIN FREE-SUGAR FREE  
KEEP OUT OF THE REACH OF CHILDREN

17856-0141-05  
SILAPAP

Dosage: 5 ML

Qty: 72 Cups



GTIN: 1785601415  
S/N: 00000000000009  
Exp: 10/03/20  
Lot: 000000

OTC



17856014105

Packaged by: Unit Dose Solution  
Morrisville, NC 27560  
Distributed by: AtlanticBiologica  
Corp, Miami FL 33179

Call to Reorder: 800.509.7592



17856-0141-07



ACETAMINOPHEN (SILAPAP) 40  
MG/1.25 ML ORAL LIQUID

Rev.01/19

See package insert for indications and dosage schedule

Store at room temperature 20°-25° (68°-77°F) PAIN  
RELIEVER. FEVER REDUCER  
ALCOHOL FREE-ASPIRIN FREE-SUGAR FREE  
KEEP OUT OF THE REACH OF CHILDREN

17856-0141-07  
SILAPAP

Dosage: 1.25 ML

Qty: 120 Syringes



GTIN: 1785601417  
S/N: 00000000000013  
Exp: 10/03/19  
Lot: 000000

OTC



17856014107

Packaged by: Unit Dose Solutions  
Morrisville, NC 27560

Distributed by: AtlanticBiologicals  
Corp, Miami FL 33179

Call to Reorder: 800.509.7592

### CHILDRENS SILAPAP

acetaminophen liquid

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-0141(NDC:54838-144)
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY (cherry flavor)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-0141-1	50 in 1 BOX, UNIT-DOSE	01/15/2021	
1		20.31 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:17856-0141-2	50 in 1 BOX, UNIT-DOSE	01/15/2021	
2		31.25 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
3	NDC:17856-0141-3	50 in 1 BOX, UNIT-DOSE	01/15/2021	
3		15.6 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
4	NDC:17856-0141-4	120 in 1 BOX, UNIT-DOSE	01/15/2021	
4		2.5 mL in 1 SYRINGE; Type 0: Not a Combination Product		
5	NDC:17856-0141-5	72 in 1 BOX, UNIT-DOSE	01/15/2021	
5		5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
6	NDC:17856-0141-6	48 in 1 BOX, UNIT-DOSE	01/15/2021	
6		5 mL in 1 SYRINGE; Type 0: Not a Combination Product		
7	NDC:17856-0141-7	120 in 1 BOX, UNIT-DOSE	01/15/2021	
7		1.25 mL in 1 SYRINGE; Type 0: Not a Combination Product		
8	NDC:17856-0141-8	120 in 1 BOX, UNIT-DOSE	01/15/2021	
8		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	01/15/2021	



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

**Establishment**

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	relabel(17856-0141) , repack(17856-0141)

Revised: 1/2021

ATLANTIC BIOLOGICALS CORP.