

## **CHILDRENS MAPAP ACETAMINOPHEN- acetaminophen liquid**

**Atlantic Biologicals Corps**

*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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### **Childrens MĀPAP Acetaminophen Liquid<sup>®</sup>**

#### **Active ingredient (in each TSP (5 mL))**

Acetaminophen 160 mg

#### **Purpose**

Fever reducer-Pain reliever

#### **Uses**

Temporarily relieves minor aches and pains due to:

- the common cold
- flu
- headache
- sore throat
- toothache

Temporarily reduces fever

#### **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

##### **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 product containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist

liver disease **Ask a doctor before use if your child has**

taking the blood thinning drug warfarin. **Ask a doctor or pharmacist before use if your child is**

##### **Stop use and ask a doctor if**

- pain gets worse or last for more than 5 days
- fever gets worse or last for more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

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

**Keep out of the 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 (1-800-222-1222) right away. Quick medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

### **Directions**

- **this product does not contain directions or complete warnings for adult use**
- find right dose on chart
- if possible, use weight to dose; otherwise, use age
- if needed, repeat dose every 4 hours
- do not use more than 5 doses in 24 hours

<b>Weight</b>	<b>Age</b>	<b>Dose</b>
under 24 lbs	Under 2 years	ask a doctor
24 to 35 lbs	2 to 3 years	1 TSP (5 mL)
36 to 47 lbs	4 to 5 years	1 1/2 TSP (7.5 mL)
48 to 59 lbs	6 to 8 years	2 TSP (10 mL)
60 to 71 lbs	9 to 10 years	2 1/2 TSP (12.5 mL)
72 to 95 lbs	11 years	3 TSP (15 mL)

### **Other information**

- sodium 1mg **Each TSP(5 mL) contains:**
- **TAMPER-EVIDENT: Do not use this product if inner foil seal over mouth of the bottle is cut, torn, broken, or missing.**
- store at 20° - 25°C (68° – 77°F)
- this product is not the same concentration as Infants' Drops. For accurate dosing, follow the dosing instructions on this label.

### **Inactive ingredients**

artificial flavor, citric acid anhydrous, D&C Red #33, FD&C Red #40, glycerin, polyethylene glycol 1450, propylene glycol, purified water, sodium benzoate, sodium saccharin, sorbitol

### **Questions?**

**To Report Adverse Drug Event call 1-800-616-2471 Weekdays, 9AM - 5PM Eastern Time**

**CHILDRENS MAPAP ACETAMINOPHEN (ACETAMINOPHEN) LIQUID**

**NDC 17856-0985-04**

**Mapap™ Liquid**

(ACETAMINOPHEN)

**40 mg per 1.25 mL**

Fever Reducer / Pain Reliever

Cherry Flavor

Alcohol Free / Aspirin Free

**UNIT DOSE 1.25 mL ORAL SYRINGE**

**PACKAGING INFORMATION:**

Dosage per Oral Syringe: 1.25 mL

Oral Syringe(s) per Case: 120

**See package insert for Drug Facts.**

**Other Information:**

Store at 20°C-25°C (68°F-77°F)

Each TSP (5mL) contains: Sodium 1 mg.

**KEEP MAPAP™ LIQUID AND ALL DRUGS  
OUT OF THE REACH OF CHILDREN**

Dist by: Major Pharmaceuticals  
Livonia, MI 48150 USA  
Repackaged by: UDose LLC, Miami, FL 33179  
Distributed by: Atlantic Biologicals Corp.  
20101 NE 16th Place  
Miami, FL 33179

**\*Retain box label and package insert for drug information.**

Questions or Comments:  
Call 1-800-509-7592

UDose LLC Lot No:  
Mfg Lot No:  
Exp. Date.



17856098504

**PKG BY: UDOSE LLC., MIAMI, FL 33179  
DIST BY: ATLANTIC BIOLOGICALS**



**NDC: 17856-0985-07**

**MAPAP LIQUID**

**(ACETAMINOPHEN 160 mg per 5 mL)**

**DELIVERS 5 mL**

**CHILDRENS MAPAP ACETAMINOPHEN (ACETAMINOPHEN) LIQUID**

**NDC 17856-0985-09**

**MAPAP™ LIQUID**

(Acetaminophen)

**DELIVERS 80 mg / 2.5 mL ORAL ENFIT SYRINGE**

PAIN RELIEVER-FEVER REDUCER

Alcohol-Free, Aspirin-Free

Cherry Flavored Liquid

**UNIT DOSE**

**DOSAGE:**

Syringe Size: 2.5 mL

Syringe(s) per case: 120

See package insert for indications and dosage schedule.

Other information:

**Store at 20°-25°C (68°-77°F)**

**Each TSP (5mL) contains: sodium 1mg**

**KEEP MAPAP LIQUID AND ALL DRUGS OUT OF REACH OF CHILDREN.**

**Repackaged by:** Unit Dose Solutions, Inc. Morrisville, NC 27560

**Distributed by:** Atlantic Biologicals Corp.  
20101 N.E. 16th Place  
Miami, FL 33179

**Questions or Comments:  
Call 1-800-509-7592**

\*Retain box label and insert for drug information.

UDS Lot No: XXXXXX

MFG Lot No: XXXXXX

Exp. Date: XX/XX/XXXX



17856098509

**CHILDRENS MAPAP ACETAMINOPHEN**

acetaminophen liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:17856-0985(NDC:0904-1985)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	160 mg in 5 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Sorbitol</b> (UNII: 506T60A25R)	
<b>Sodium Benzoate</b> (UNII: OJ245FE5EU)	
<b>Anhydrous citric acid</b> (UNII: XF417D3PSL)	
<b>FD&amp;C Red no. 40</b> (UNII: WZB9127XOA)	
<b>Water</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>Propylene glycol</b> (UNII: 6DC9Q167V3)	
<b>PRUNUS SEROTINA BARK</b> (UNII: 5D48E975HA)	
<b>POLYETHYLENE GLYCOL 1450</b> (UNII: OJ4Z5Z32L4)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	

### Product Characteristics

<b>Color</b>	RED	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-0985-7	5 mL in 1 SYRINGE; Type 0: Not a Combination Product	05/05/2015	
2	NDC:17856-0985-8	6.25 mL in 1 SYRINGE; Type 0: Not a Combination Product	07/22/2016	
3	NDC:17856-0985-9	2.5 mL in 1 SYRINGE; Type 0: Not a Combination Product	11/12/2018	
4	NDC:17856-0985-2	2.5 mL in 1 SYRINGE; Type 0: Not a Combination Product	07/22/2016	
5	NDC:17856-0985-5	7.5 mL in 1 SYRINGE; Type 0: Not a Combination Product	07/22/2016	
6	NDC:17856-0985-4	1.25 mL in 1 SYRINGE; Type 0: Not a Combination Product	09/08/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	08/20/2012	

**Labeler** - Atlantic Biologicals Corps (047437707)

**Registrant** - Atlantic Biologicals Corps (047437707)

### Establishment

Name	Address	ID/FEI	Business Operations
Atlantic Biologicals Corps		047437707	RELABEL(17856-0985) , REPACK(17856-0985)