

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.

Childrens MĀPAP Acetaminophen Liquid[®]

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

| Weight | Age | Dose |
|---------------|---------------|---------------------|
| 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 17856-1986-02

Mapap™ Liquid
(ACETAMINOPHEN)

499.2 mg / 15.6 mL

Fever Reducer / Pain Reliever
Cherry Flavor

Alcohol-Free / Aspirin-Free

UNIT DOSE 15.6 mL CUP

PACKAGING INFORMATION:

Dosage per Cup: 15.6 mL
Cup(s) per Case: 50

See package insert for Drug Facts

Other information:

Store at 20°- 25°C (68°- 77°F).

Each TSP (5 mL) contains: sodium 1 mg

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

Dist by: Major Pharm, 31778 Enterprise Drive, Livonia, MI 48150

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

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

*Retain box label and package insert for drug information.

Questions or Comments:

Call 1-800-509-7592 (Ext. 200)

UDS Lot No: XXXXXX
MFG Lot No: XXXXXX
Exp. Date: XX/XX/XXXX



17856198602

CHILDRENS MAPAP ACETAMINOPHEN

acetaminophen liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|-------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:17856-1986(NDC:0904-1985) |
| 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 |
|---|----------|
| Glycerin (UNII: PDC6A3C0OX) | |
| Sorbitol (UNII: 506T60A25R) | |
| Sodium Benzoate (UNII: OJ245FE5EU) | |
| Anhydrous citric acid (UNII: XF417D3PSL) | |
| FD&C Red no. 40 (UNII: WZB9127XOA) | |
| Water (UNII: 059QF0KO0R) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| Propylene glycol (UNII: 6DC9Q167V3) | |
| PRUNUS SEROTINA BARK (UNII: 5D48E975HA) | |
| POLYETHYLENE GLYCOL 1450 (UNII: OJ4Z5Z32L4) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|--|
| Color | RED | Score | |
| Shape | | Size | |
| Flavor | CHERRY | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:17856-1986-2 | 50 in 1 CASE | 03/01/2016 | |
| 1 | | 15.6 mL in 1 CUP, UNIT-DOSE ; Type 0: Not a Combination Product | | |
| 2 | NDC:17856-1986-3 | 50 in 1 CASE | 03/01/2016 | |
| 2 | | 31.2 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 | 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(17856-1986) , REPACK(17856-1986) |

Revised: 3/2016

Atlantic Biologicals Corps