CHILDRENS MAPAP ACETAMINOPHEN- acetaminophen liquid
NuCare Pharmaceuticals,Inc.

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

Drug Facts

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

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.

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.

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

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

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

PRINCIPAL DISPLAY PANEL - 118mL Bottle Carton

CHILDRENS MAPAP ACETAMINOPHEN

acetaminophen liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-3389(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 (UNII: FST467XS7D)	
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:68071-3389-4	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/18/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/20/2012	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-3389)

Revised: 2/2021 NuCare Pharmaceuticals,Inc.