

CHILDRENS MAPAP- acetaminophen liquid

A-S Medication Solutions

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.

Children's Māpap[®] ACETAMINOPHEN LIQUID

Drug Facts

Active ingredient (in each 5mL)

Acetaminophen 160 mg

Purpose

Pain reliever - Fever reducer

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

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 product containing acetaminophen (prescription or nonprescription). 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 (see overdose warning)

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.

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
- mL = millileter
- if needed, repeat dose every 4 hours
- do not use more than 5 doses in 24 hours
- use enclosed dosing cup only. Do not use any other device

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

Other information

- each 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, saccharin sodium, sodium benzoate, sorbitol

Questions or Comments?

Call 1-800-616-2471

HOW SUPPLIED

Product: 50090-2588

NDC: 50090-2588-0 118 mL in a BOTTLE

Acetaminophen



CHILDRENS MAPAP

acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-2588(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:50090-2588-0	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/02/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/01/2015	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-2588)