

CHILDRENS MAPAP- acetaminophen tablet, chewable

Major Pharmaceuticals

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.

Major 44-452

Active ingredient (in each chewable tablet)

Acetaminophen 80 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - toothache
 - sore throat
 - the common cold
 - flu
- 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 drug 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 dosage.

Stop use and ask a doctor if

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

These could be signs of a serious condition.

Keep out of reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed**
- find the right dose on chart below. If possible, use weight to dose; otherwise, use age.
- chew or crush tablets completely before swallowing; do not swallow tablets whole
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give for more than 5 days unless directed by a doctor

Weight (lb)	Age (yr)	Dose (chewable tablets)*
Under 24	Under 2	Ask a doctor
24-35	2-3	2 tablets
36-47	4-5	3 tablets
48-59	6-8	4 tablets
60-71	9-10	5 tablets
72-95	11	6 tablets

*or as directed by a doctor

Other information

- avoid high humidity
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

citric acid, crospovidone, D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrans hydrated, ethylcellulose, FD&C blue #1 aluminum lake, flavors, magnesium stearate, mannitol, polyethylene, stearic acid, sucralose

Questions or comments?

(800) 616-2471

Principal Display Panel

MAJOR®

NDC 0904-5791-46

*Children's
Māpap®*

ACETAMINOPHEN

80 mg Chewable Tablets

Pain reliever / Fever reducer

ASPIRIN FREE • IBUPROFEN FREE

AGES 2-6

30 Chewable Tablets

Chew or crush
tablets completely
before swallowing.

Grape Flavor

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS
BROKEN OR MISSING**

50844 REV0119H45201

Distributed by **MAJOR® PHARMACEUTICALS**

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152 USA M-17 Rev. 02/19

Re-order No. 006446

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Drug Facts (continued)

Questions or comments? (800) 616-2471

Drug Facts (continued)

Drug Facts (continued)

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 dosage.

Stop use and ask a doctor if

- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- itchiness or swelling is present

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B-1212-452-01
REV0119H45201

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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CHILDRENS MAPAP

acetaminophen tablet, chewable

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0904-5791

Route of Administration

ORAL

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	80 mg	
Inactive Ingredients				
Ingredient Name		Strength		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
D&C RED NO. 27 (UNII: 2LRS185U6K)				
D&C RED NO. 30 (UNII: 2S42T2808B)				
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MANNITOL (UNII: 3OWL53L36A)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
CROSPVIDONE (UNII: 2S7830E561)				
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)				
Product Characteristics				
Color	PURPLE	Score	no score	
Shape	ROUND	Size	13mm	
Flavor	GRAPE	Imprint Code	44;452	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-5791-46	1 in 1 CARTON	12/06/2004	
1		30 in 1 BOTTLE, PLASTIC; 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	12/06/2004		

Labeler - Major Pharmaceuticals (191427277)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(0904-5791)

Establishment

Name	Address	ID/FEI	Business Operations
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LNK International, Inc.		038154464	PACK(0904-5791)
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Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(0904-5791)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(0904-5791)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(0904-5791)

Revised: 4/2019

Major Pharmaceuticals