

CHILDRENS MAPAP- acetaminophen tablet, chewable Proficient Rx LP

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 44-450-children

Active ingredient (in each chewable tablet)

Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - sore throat
 - flu
 - toothache
 - the common cold
- 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	1 tablet
36-47	4-5	1 1/2 tablets
48-59	6-8	2 tablets
60-71	9-10	2 1/2 tablets
72-95	11	3 tablets

*or as directed by a doctor

Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- 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, dextrates hydrated, ethylcellulose, flavor, magnesium stearate, mannitol, polyethylene, stearic acid, sucralose

Questions or comments?

(800) 616-2471

Principal Display Panel

MAJOR®

NDC 71205-322-24

Children's

Māpap®

ACETAMINOPHEN

160 mg Chewable Tablets

Pain reliever / Fever reducer

ASPIRIN FREE • IBUPROFEN FREE

AGES

2-11

Chew or crush tablets completely before swallowing.

24 Chewable Tablets,

160 mg EACH

Bubble Gum Flavor

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS

TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

Distributed by **MAJOR® PHARMACEUTICALS**

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152 USA M-17



Relabeled by **PROFICIENT RX LP**

Thousand Oaks, CA 91320

Rev. 11/18

Re-order No. 700846

50844 REV1018B45008

Scan Here   NDC 71205-322-24 Relabeled By Proficient Rx LP
Thousand Oaks, CA 91320

Mapap Acetaminophen 160mg
#24 Chewable Tablets

Each chewable tablet contains: Acetaminophen 160 mg Pain reliever/ fever reducer

Pink, round, bubble gum flavored tablet, scored in 2 pieces with imprint code "44 450"


Product ID: SA032224 **Ages 2-11**

Dist. By: MAJOR PHARMACEUTICALS 17177 N Laurel Park Drive, Suite 233 Livonia, MI 48152 USA
Store at 25°C (77°F) Keep medication out of the reach of children

Mapap Acetaminophen 160mg #24 Chewable Tablets
Lot # 00000 SN# MASTER Exp.00/00/00
NDC 71205-322-24

Mapap Acetaminophen 160mg #24 Chewable Tablets
Lot # 00000 SN# MASTER Exp.00/00/00
NDC 71205-322-24

Mapap Acetaminophen 160mg #24 Chewable Tablets
Lot # 00000 SN#MASTER Exp.00/00/00
NDC 71205-322-24

 GTIN: 00371205322243
SN# MASTER
Exp. 00/00/00
Lot # 00000

CHILDRENS MAPAP

acetaminophen tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71205-322(NDC:0904-6645)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPVIDONE (UNII: 2S7830E561)	

D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

Product Characteristics

Color	PINK	Score	2 pieces
Shape	ROUND	Size	16mm
Flavor	BUBBLE GUM	Imprint Code	44;450
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71205-322-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	02/25/2005	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(71205-322) , RELABEL(71205-322)

Revised: 9/2021

Proficient Rx LP