

**CHILDRENS CHEWABLE 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 Children's Chewable Mapap

Drug Facts

Active ingredient (in each chewable tablet)

Acetaminophen 80 mg

Purposes

Pain Reliever/Fever Reducer

Uses

- temporarily relieves minor aches and pain 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 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 dose (see overdose warning)

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.

Overdose warning: In the case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical even if you do not notice any signs or symptoms.

Directions

- **this products does not contain directions or complete warnings for adult use.**
- find right dose on the chart below. If possible, use weight to dose; otherwise, use age.
- chew before swallowing
- if needed, 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	Age	Dosage
Under 24 lbs	Under 2 years	Ask a doctor
24-35 lbs	2-3 years	2 tablets
36-47 lbs	4-5 years	3 tablets
48-59 lbs	6-8 years	4 tablets
60-71 lbs	9-10 years	5 tablets
72-95 lbs	11 years	6 tablets

Other information

- Phenylketonurics: Contain Phenylalanine 14 mg per tablet
- Store at room temperature in a dry place

Inactive ingredients Aspartame, Colloidal Silica, D&C Red # 27 Lake, Hypromellose, Magnesium Stearate, Mannitol, Natural & Artificial Berry Flavors, Povidone, Pregelatinized Starch, Sodium Chloride, Sodium Starch Glycolate, Sorbitol, Stearic Acid and Sucralose.

Questions or comments?

Call: (800) 616-2471

Distributed by:

MAJOR PHARMACEUTICALS

17177 N LAUREL PARK DRIVE, SUITE 233

LIVONIA, MI 48152

Relabeled by:

Proficient Rx LP

Thousand Oaks, CA 91320

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

MAJOR®

NDC 63187-968-30

See New Warnings Information

Children's Chewable

Mapap Acetaminophen

Fever reducer/ Pain reliever

ASPIRIN FREE • IBUPROFEN FREE

NATURAL & ARTIFICIAL BERRY FLAVORS

30 Tablets, 80 mg EACH

AGES 2-11



NDC 63187-968-30

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

Mapap Acetaminophen 80mg

#30 Chewable Tablets

Acetaminophen 80 mg Pain Reliever/ Fever Reducer
Fruit Flavor

Pink, round, unscored, biconvex tablet with imprint code "1G"

Product ID: RA096830

AGES 2-6

Dist. By: MAJOR PHARMACEUTICALS 31778 ENTERPRISE DRIVE LIVONIA, MI 48150 USA

Store at room temperature in a dry place Keep medication out of the reach of children

Mapap Acetaminophen 80mg
#30 Chewable Tablets
Lot #:00000 SN# MASTER
NDC 63187-968-30 Exp:00/00/00

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Thousand Oaks, CA 91320

CHILDRENS CHEWABLE MAPAP

acetaminophen tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63187-968(NDC:0904-5256)
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
ASPARTAME (UNII: Z0H242BBR1)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

Product Characteristics

Color	pink	Score	no score
Shape	ROUND (ROUND BICONVEX TABLET)	Size	10mm
Flavor		Imprint Code	1G
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-968-30	1 in 1 CARTON	01/01/2018	
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	05/04/2011	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(63187-968) , RELABEL(63187-968)