

CHILDRENS MAPAP- acetaminophen tablet, chewable

Major Pharmaceuticals

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.

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

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center 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

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?

1-800-426-9391

Principal Display Panel

MAJOR®

NDC 0904-6645-24

Compare to the active ingredient
in Children's Tylenol® Chewables†

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**

Actual Size

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

Indianapolis, IN 46268

(800) 616-2471

www.major-rugby.com

Rev. 11/24 M-17 Re-order No. 700846

†This product is not manufactured or distributed by
Kenvue Inc., owner of the registered trademark
Children's Tylenol® Chewables.

50844 REV0424E45008

Drug Facts
KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Active ingredient
(in each chewable tablet)
Acetaminophen 160 mg.....Pain reliever/fever reducer

Purpose
Severe liver damage may occur if your child takes more than 5 doses in 24 hours, which is the maximum daily amount

Uses
temporarily relieves minor aches and pains due to:
■ headache ■ sore throat ■ flu
temporarily reduces fever

Warnings
Liver warning: This product contains acetaminophen.
■ temporarily reduces fever
■ headache ■ sore throat ■ flu
■ the common cold
■ toothache

Drug Facts (continued)
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.

MAJOR[®]

NDC 0904-6645-24
Compare to the active ingredient in Children's Tylenol[®] Chewables¹

Children's Māpap[®]

ACETAMINOPHEN

160 mg Chewable Tablets

Pain reliever / Fever reducer
ASPIRIN FREE • IBUPROFEN FREE

AGES 2-11

24 Chewable Tablets, 160 mg EACH

Actual Size



Bubble Gum Flavor

Chew or crush tablets completely before swallowing.

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

Drug Facts (continued)
Questions or comments?
1-800-426-9391

This product is not manufactured or distributed by Kenvue Inc., owner of the registered trademark Children's Tylenol[®] Chewables.
50844 REV0424E45008

09046 64524 3

Drug Facts (continued)

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.

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 lasts more than 3 days
■ fever gets worse or lasts more than 3 days
■ redness or swelling is present
■ any new symptoms appear

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center 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

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, croscopolone, D&C red #27 aluminum lake, D&C red #30 aluminum lake, extrates hydrate, ethylcellulose, flavor, magnesium stearate, mannitol, polyethylene, stearic acid, sucralose

Drug Facts (continued)
■ repeat dose every 4 hours while symptoms last
■ do not give more than 5 times in 24 hours

Weight (lb)	Age (yr)	Dose (chewable tablets)*
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* as directed by a doctor

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No Print Area
Lot no. & Exp. Date

B-1212-450-08-R
REV0424E45008

Major 44-450

CHILDRENS MAPAP

acetaminophen tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
D&C RED NO. 30 ALUMINUM LAKE (UNII: GE75M6YV5W)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

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:0904-6645-24	4 in 1 CARTON	02/25/2005	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	02/25/2005	

Labeler - Major Pharmaceuticals (191427277)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(0904-6645)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(0904-6645) , pack(0904-6645)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(0904-6645)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(0904-6645)