

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.
- 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 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
- 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 0904-6645-24

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

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

www.majorpharmaceuticals.com

M-17 Rev. 06/22

Re-order No. 700846

†This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Children's Tylenol®. 50844 REV0522D45008

Drug Facts COMPLETE PRODUCT INFORMATION

Active ingredient
(in each chewable tablet)
Acetaminophen 160 mg.....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.
Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:
rash
skin reddening blisters
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.

Drug Facts (continued)
Severe liver damage may occur if your child takes more than 5 doses in 24 hours, which is the maximum daily amount.
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MAJOR

NDC 0904-6645-24
Compare to the active ingredient
in Children's Tylenol™

Children's Māpap[®] ACETAMINOPHEN 160 mg Chewable Tablets

Pain reliever / Fever reducer
ASPIRIN FREE • IBUPROFEN FREE

**AGES
2-11**

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before swallowing.

**24 Chewable Tablets,
160 mg EACH**



No Print Area
Lot no. & Exp. Date

Distributed by: MAJOR[®] PHARMACEUTICALS
Indianapolis, IN 46268
www.majorpharmaceuticals.com
M-17 Rev. 08/22
Re-order No. 703946

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

B-1212-450-08-R
REV0522D45008



This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Children's Tylenol[®], 50844 REV0522D45008

Drug Facts (continued)

Inactive ingredients citric acid, croscollon, D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrans hydrated, ethylcellulose, flavor, magnesium stearate, mannitol, polyethylene, stearyl acid, sucralose

Questions or comments?
(800) 616-2471

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. If your child is allergic to acetaminophen or any of the inactive ingredients in this product, ask a doctor or pharmacist 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 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

Other information

TAMPER EVIDENT: DO NOT USE IF OUTER OR PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN

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do not give for more than 5 days unless directed by a doctor

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 (UNII: 2S42T2808B)	
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)

Revised: 8/2023

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