

## **CHILDRENS CHEWABLE 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.*

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### **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.

<b>Weight</b>	<b>Age</b>	<b>Dosage</b>
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**

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

**MAJOR®**

NDC 0904-5256-46

**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



**CHILDRENS CHEWABLE MAPAP**

acetaminophen tablet, chewable

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-5256
<b>Route of Administration</b>	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)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POVIDONE (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:0904-5256-46	1 in 1 CARTON	05/04/2011	11/30/2020
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	11/30/2020

**Labeler** - Major Pharmaceuticals (191427277)

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