MAPAP EXTRA STRENGTH- acetaminophen capsule 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.

0617 - Major

Drug Facts

Active Ingredient (in each banded capsule)

Acetaminophen 500 mg

Purpose

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Pain reliever/ Fever reducer

Uses

Temporarily reduces fever and relieves minor aches and pains due to:

- headache
- muscular aches
- common cold
- toothache
- backache
- minor pain of arthritis
- premenstrual and menstrual cramps

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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.

Do not use

- with any other drugs containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist
- if you are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if you have

liver disease

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin

Stop use and ask a doctor if

- pain gets worse or lasts for more than 10 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.

If pregnant or breast-feeding,

ask a health professional before use.

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 for adults as well as for children even if you do not notice any signs or symptoms.

Directions

Do not take more than directed (see overdose warning).

adults and children 12 years and over:

- take 2 capsules every 6 hours while symptoms last
- Do not take more than 6 capsules in 24 hours, unless directed by a doctor
- Do not take for more than 10 days unless directed by a doctor

children under 12 years: ask a doctor

Other information

• store at room temperature

Inactive Ingredients

FD&C Blue #1, FD&C Red #40, Gelatin, Polyvinylpyrrolidone, Pregelatinized Starch, Sodium Starch Glycolate, Stearic Acid and Titanium Dioxide

Questions?

Call: (800) 616-2471

Distributed by: Major® Pharmaceuticals

17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152 USA

Re-order No. 700691 Rev.05/19 M-29 4050-05-19

Major

NDC 0904-1987-60

EXTRA STRENGTH

Mapap

Acetaminophen 500 mg Each

CAPSULES SAFETY SEALED FOR YOUR PROTECTION

SEE NEW WARNINGS INFORMATION AND DIRECTIONS

ASPIRIN FREE

Strong Pain & Fever Relief

100 CAPSULES



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 for adults as well as Ask a doctor or pharmacist before use if you are for children even if you do not notice any signs FD&C Red #40_Gelatin, Polyvinylpyrrolidone, Pregelatinized Starch, Sodium Starch Glycolate, pain gets worse or lasts more than 10 days fever gets worse or lasts more than 3 days new symptoms occur. do not take more than directed (see overdose of not take more than 6 capsules in 24 hours, unless directed by a doctor on take for more than 10 days unless **If pregnant or breast-feeding**, ask a health Ask a doctor before use if you have liver redness or swelling is present These could be signs of a serious condition. nactive ingredients FD&C Blue#1 adults and children 12 years and over **children under 12 years:** ask a doctor take 2 capsules every 6 hours while Other information store at room aking the blood thinning drug warfarin Drug Facts (continued) **Questions or comments?** Call (800) 616-2471 tearic Acid and Titanium Dioxide professional before use. Keep out of reach of children. Stop use and ask a doctor if directed by a doctor symptoms last

MAPAP EXTRA STRENGTH

acetaminophen capsule

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-1987
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients		
Ingredient Name	Strength	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GELATIN (UNII: 2G86QN327L)		
POVIDONE K30 (UNII: U725QWY32X)		
STARCH, CORN (UNII: O8232NY3SJ)		
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

Product Characteristics				
Color	white, red	Score	no score	
Shape	CAPSULE	Size	22mm	
Flavor		Imprint Code	CPC;617	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-1987-60	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/22/1997	
2	NDC:0904-1987-80	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/29/2001	04/30/2017

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/22/1997	

Labeler - Major Pharmaceuticals (191427277)

Revised: 5/2020 Major Pharmaceuticals