

## **MAPAP EXTRA STRENGTH- acetaminophen capsule**

### **State of Florida DOH Central Pharmacy**

*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.*

-----

### **Extra Strength APAP Capsules**

#### ***Drug Facts***

#### **Active Ingredient**

(in each capsule)

Acetaminophen 500 mg

#### **Purposes**

Analgesic, Antipyretic

#### **Uses**

- temporarily relieves minor aches and pains due to
- the common cold
- headache
- toothache
- muscular aches
- backache
- minor pain of arthritis
- premenstrual and menstrual cramps
- temporarily reduces fever

#### **Warnings**

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

- more than 8 capsules in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

#### **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 before use if you are**

taking the blood thinning drug warfarin

**Stop use and ask a doctor if**

- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts more than 3 days

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** Taking more than the recommended dose (overdose) may cause liver damage. In case of In case of overdose, get medical help or contact Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

**Directions**

adults and children 12 years of age and over	take 2 capsules every 4 hour to 6 hours, not to exceed 8 capsules in 24 hours. Do not take for more than 10 days unless directed by a doctor.
children under 12 years of age	Do not use Extra Strength product in children 12 years of age; this will provide more than the recommended dose (overdose) of pain reliever and could cause liver damage.

**DO NOT EXCEED RECOMMENDED DOSE****Other information**

- store at room temperature, USP
- use by expiration date on pckage
- do not use if capsule band or imprinted safety seal under cap is broken or missing
- **side effects occur**
- **You may report side effects at 1-800-616-2471 (Toll Free)**

**Inactive Ingredients**

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

\*Major Extra Strength Mapap is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Extra Strength Tylenol®.

Distributed by:

MAJOR PHARMACEUTICALS

Livonia, MI 48150 USA

This Product was Repackaged By:

**State of Florida DOH Central Pharmacy**

104-2 Hamilton Park Drive

Tallahassee, FL 32304  
 United States

They are supplied by **State of Florida DOH Central Pharmacy** as follows:

NDC	Strength	Quantity/Form	Color	Source Prod. Code
53808-0822-1	500 mg	30 Capsules in a Blister Pack	RED	0904-1987

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**



<b>MAPAP EXTRA STRENGTH</b>			
acetaminophen capsule			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53808-0822(NDC:0904-1987)
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>
	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 DIOXIDE (UNII: 15FIX9V2JP)		

## Product Characteristics

<b>Color</b>	RED	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	22mm
<b>Flavor</b>		<b>Imprint Code</b>	CPC;617
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53808-0822-1	30 in 1 BLISTER PACK		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	01/01/2013	

**Labeler** - State of Florida DOH Central Pharmacy (829348114)

## Establishment

Name	Address	ID/FEI	Business Operations
State of Florida DOH Central Pharmacy		829348114	repack(53808-0822)

Revised: 8/2013

State of Florida DOH Central Pharmacy