# MAPAP- acetaminophen tablet A-S Medication Solutions

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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# **Drug Facts**

# Active ingredient (in each tablet)

Acetaminophen 325 mg

# **Purposes**

Pain reliever/fever reducer

Aspirin-Free Pain Reliever/ Fever Reducer

#### Uses

for the temporary relief of minor aches and pains due to:

- Headache
- Muscular aches
- Backache
- Minor pain of arthritis
- The common cold
- Toothache
- Premenstrual and menstrual cramps

Temporarily reduces fever.

# **Warnings**

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

- adult takes more than 12 tablets in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

#### Do not use

- with any other drug containing acetaminophen (prescription or non prescription). 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 the user has

liver disease.

### Ask a doctor or pharmacist before use if the user is

taking the blood thinning drug warfarin.

# Stop use and ask a doctor if

- Pain gets worse or lasts more than 10 days in adults and children
- Pain gets worse or lasts more than 5 days in children under 12 years
- 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:

Taking more than the recommended dose (overdose) may cause liver damage. In 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

AGE	DOSE
Adults and children 12 years and over	
	<ul> <li>Take 2 tablets every 4 to 6 hours while symptoms last</li> <li>Do not take more than 12 tablets in 24 hours</li> </ul>
Children 6 to 11 years	
	<ul> <li>Take 1 tablet every 4 to 6 hours while symptoms last</li> <li>Do not take more than 5 tablets in 24 hours</li> </ul>
Children under 6 years	Do not use adult Regular Strength products in children under 6 years of age; this will provide more than the recommended dose (overdose) of acetaminophen and may cause liver damage.

#### Other information

• Store at room temperature

# **Inactive ingredients**

Povidone, Pregelatinized Starch, Sodium Starch Glycolate, Stearic Acid

# Questions or comments?

Adverse Drug Event call (800) 616-2471

Tamper Evident: Do not use if sealed blister units are broken or damaged.

LHC54731216

Distributed by:

MAJOR® PHARMACEUTICALS

17177 N Laurel Park Dr., Suite 233

Livonia, MI 48152 USA

#### **HOW SUPPLIED**

Product: 50090-0266

NDC: 50090-0266-3 30 TABLET in a BOTTLE NDC: 50090-0266-1 15 TABLET in a BOTTLE

#### **ACETAMINOPHEN**



# MAPAP acetaminophen tablet Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:50090-0266(NDC:0904-1982)

ORAL

# Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg

Inactive Ingredients		
Ingredient Name	Strength	
PO VIDO NE K12 (UNII: 333AG72FWJ)		
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
STARCH, CORN (UNII: O8232NY3SJ)		

Product Characteristics			
Color	WHITE	Score	no score
Shape	ROUND (round flat faced beveled edge)	Size	10 mm
Flavor		Imprint Code	GPI;A325
Contains			

l	Packaging				
l	# Item Code	Item Code Package Description		<b>Marketing End Date</b>	
l	1 NDC:50090-0266-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/28/2014		
l	2 NDC:50090-0266-1	15 in 1 BOTTLE; Type 0: Not a Combination Product	11/28/2014	12/31/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/21/2011	

# Labeler - A-S Medication Solutions (830016429)

Establishment				
Name	Address	ID/FEI	Business Operations	
A-S Medication Solutions		830016429	RELABEL(50090-0266), REPACK(50090-0266)	

Revised: 9/2017 A-S Medication Solutions