

EXTRA STRENGTH MAPAP - acetaminophen tablet, film coated
H.J. Harkins Company, Inc.

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.

Drug Facts

Active Ingredient (in each caplet)

Acetaminophen 500 mg

Purpose

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 you take

- more than 8 caplets 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 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 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 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: Taking more than the recommended dose (overdose) may cause liver damage. 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

Adults and children 12 years and over:

- take 2 caplets every 4 to 6 hours while symptoms last
- do not take more than 8 caplets in 24 hours
- Do not take for more than 10 days unless directed by a doctor

Children under 12 years: do not use adult Extra Strength product in children under 12 years of age; this will provide more than the recommended dose (overdose) of acetaminophen and may cause liver damage.

Other information

- **Do not use if imprinted safety seal under cap is broken or missing.**
- store at room temperature

Inactive ingredients

Hypromellose, Polyethylene Glycol, Povidone, Pregelatinized Starch, Sodium Starch Glycolate, Stearic Acid

Questions?

Adverse Drug Events call (800) 616-2471

Repacked by:

H.J. Harkins Company, Inc.

513 Sandydale Drive

Nipomo, CA 93444

Principal Display Panel of Extra Strength Mapap 500 mg Caplets

NDC 0904-1983-60

MAJOR®

**See New Warnings
Information**

Extra Strength
Mapap

ASPIRIN FREE
ACETAMINOPHEN

STRONG PAIN &
FEVER RELIEF

CAPLETS

Compare to active ingredient in Extra Strength Tylenol® Caplets*

*This product is not manufactured or distributed by McNeil Consumer Products Co., owner of the registered trademark Tylenol®.

100 Caplets
500 mg. Each
NDC 0904-1983-24

MAJOR®

EXTRA STRENGTH
Mapap

**See New Warnings
Information**

ASPIRIN FREE
ACETAMINOPHEN

STRONG PAIN & FEVER RELIEF

CAPLETS

Compare to the active ingredients in Extra Strength Tylenol® Caplets*

See New Warning Information

24 Caplets
500 mg. Each

Repacked by:

H.J. Harkins Company, Inc.

Nipomo, CA 93444

*This product is not manufactured or distributed by McNeil Consumer Products Co., owner of registered trademark Tylenol®

52959-338-40

RX Only: #XXXXXXXX

#XXX

CAUTION: Federal law PROHIBITS the transfer of this drug to anyone other than the person to whom prescribed and prohibits dispensing without a prescription unless OTC. See outsert for add'l RX info KEEP OUT OF REACH OF CHILDREN. Store in a cool dry place 68 to 77 degrees F.

ACETAMINOPHEN 500mg CAPLETS

Lot #: AEC577M

Mfg: MAJOR

Exp: 09/10

Mfg Livonia, MI

Loc.:

Compare to: Tylenol X-Str.

Mfg. NDC: 0904-1983-80

Pill ID: White Biconvex Capsule

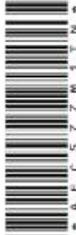
ACETAMINOPHEN 500mg CAPLETS	52959-338-40	Qty #40
09/10	Lot AEC577M	
Tylenol X-Str.	0904-1983-80	

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09/10	Lot AEC577M	
Tylenol X-Str.	0904-1983-80	

Repack: HJ Harkins Co., Inc. Nipomo, CA 93444
Dispense in tight, child & light-resistant container per USP



Take as directed by your Doctor or
See outsert for usual dosage information



EXTRA STRENGTH MAPAP

acetaminophen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52959-338(NDC:0904-1983)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE (Biconvex)	Size	17mm
Flavor		Imprint Code	GPI;A5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52959-338-00	100 in 1 BOTTLE		
2	NDC:52959-338-10	10 in 1 BOTTLE		
3	NDC:52959-338-12	12 in 1 BOTTLE		
4	NDC:52959-338-20	20 in 1 BOTTLE		
5	NDC:52959-338-24	24 in 1 BOTTLE		
6	NDC:52959-338-30	30 in 1 BOTTLE		
7	NDC:52959-338-40	40 in 1 BOTTLE		
8	NDC:52959-338-50	50 in 1 BOTTLE		
9	NDC:52959-338-60	60 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	05/04/2011	

Labeler - H.J. Harkins Company, Inc. (147681894)

Registrant - H.J. Harkins Company, Inc. (147681894)

Establishment

Name	Address	ID/FEI	Business Operations
H.J. Harkins Company, Inc.		147681894	repack, relabel

Revised: 1/2012

H.J. Harkins Company, Inc.