# PAIN RELIEVER EXTRA STRENGTH- acetaminophen capsule, liquid filled Mckesson (Sunmark)

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**

Acetaminophen 500 mg

## **Purpose**

Pain reliever/ fever reducer

#### Uses

for the temporarily relief of minor aches and pains associated with:

- headache
- minor arthritis pain
- muscular aches
- backache
- the common cold
- pre- menstrual and menstrual cramps
- toothache
- temporarily reduces fever

## **Warnings**

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

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

**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. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### Do not exceed recommended dose

#### 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 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.

### **Directions**

- adults and children 12 years and over: take 2 softgels every 6 hours while symptoms last. Do not take more than 8 softgels 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 this adult product in children under 12 years of age. This will provide more than the recommended dose (overdose) and could cause serious health problems

#### Other information

- store at controlled room temperature 15°-30°C (59°-86°F)
- do not use if imprinted safety seal under cap is broken or missing

## **Inactive ingredients**

aerosil 200, D&C Yellow #10, edible ink, gelatin, glycerin USP, povidone K- 30 USP, polyethylene glycol 400 NF, polyethylene glycol 600 NF, propylene glycol USP, Purified water USP, sorbitol special GC, and titanium dioxide USP.

#### **Principal Display Panel**

Compare to Extra Strength TYLENOL® ACTIVE INGREDIENT\*

SEE NEW WARNINGS INFORMATION

PAIN RELIEVER

Extra Strength

pain reliever & fever reducer

ACETAMINOPHEN 500 mg

Questions or comments?

call toll free 1-877-753-3935

#### KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol®

#### **Product Label**



Extra strength Pain Reliever

## PAIN RELIEVER EXTRA STRENGTH

acetaminophen capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:49348-709
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (ACETAMINO PHEN)	ACETAMINOPHEN	500 mg	

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIO XIDE		
D&C YELLOW NO. 10		
GELATIN		
GLYCERIN		
POVIDONES		
POLYETHYLENE GLYCOL 400		
POLYETHYLENE GLYCOL 600		
PROPYLENE GLYCOL		
WATER		
SORBITOL		
TITANIUM DIO XIDE		

Product Characteristic	duct Characteristics			
Color	YELLOW	Score	no score	
Shape	CAPSULE	Size	21mm	
Flavor		Imprint Code	APAP500	
Contains				

F	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:49348-709-59	1 in 1 CARTON		
1		40 in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	07/09/2010	

## Labeler - Mckesson (Sunmark) (177667227)

Revised: 9/2012 Mckesson (Sunmark)