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.

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	**Item Code (Source)**	NDC:49348-709
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POVIDONES (UNII: FZ989GH94E)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW	**Score**	no score
Shape	CAPSULE	**Size**	21mm
Flavor		**Imprint Code**	APAP500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	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)