PAIN RELIEVER PM EXTRA STRENGTH- acetaminophen, diphenhydramine hcl tablet
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.

Extra Strength Acetaminophen PM

DRUG FACTS

Active ingredients (in each caplet)

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purpose

Pain reliever

Nighttime sleep- aid

Uses

temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness.

Warnings

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

- more than 4,000 mg of acetaminophen in 24 hours
- 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 nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other product containing diphenhydramine, even one used on skin
- in children under 12 years of age

Ask a doctor before use if you have

- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- glaucoma

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- drowsiness will occur
- avoid alcoholic drinks

- do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if

- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.
- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for 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: 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 (see overdose warning)**

adults and children 12 years and over	• take 2 caplets at bedtime. Do not take more than 2 caplets of this product in 24 hours
children under 12 years	• Do not use

Other information

- store at room temperature 15°-30°C (59°-86°F)
- avoid high humidity and excessive heat

Inactive ingredients

croscarmellose sodium*, D and C Yellow #10 Aluminum Lake*, FD and C Blue #1 Aluminum Lake, FD and C Blue #2 Aluminum Lake*, hypromellose, magnesium silicate*, magnesium stearate*, microcrystalline cellulose*, mineral oil*, polyethylene glycol*, povidone, pregelatinized starch, silica*, sodium starch glycolate*, stearic acid, titanium dioxide, triacetin*

*contains one or more of these ingredients

Questions or Comments?

Call **1-877-753-3935 Monday- Friday 9AM- 5PM EST**

Principal Display Panel

Compare to EXTRA STRENTH Tylenol® PM active ingredients **

Pain Reliever PM

Extra Strength

Pain reliever /nighttime Sleep-Aid

Non- habit forming

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Tamper Evident: Do not use if imprinted safety seal under cap is broken or missing

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® PM.**

Pain Reliever PM caplets

PAIN RELIEVER PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49348-236
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	
MINERAL OIL (UNII: T5L8T28FGP)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	BLUE	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	S525;CPC752
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-236-10	1 in 1 BOX	03/26/2013	12/31/2020
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49348-236-09	1 in 1 BOX	03/26/2013	12/31/2020
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	03/26/2013	12/31/2020

Labeler - McKesson (Sunmark) (177667227)

Revised: 12/2018 McKesson (Sunmark)