

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

McKesson (Health Mart)

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 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 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 serious underlying medical illness.
- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts 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. 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&C yellow #10 aluminum lake*, FD&C blue #1 aluminum lake, FD&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 Strength Tylenol® PM caplets active ingredients†

Extra Strength

Pain Reliever PM

Acetaminophen, 500 mg

Diphenhydramine HCl, 25 mg

Pain reliever/Nighttime Sleep-Aid

Non-habit Forming

Caplets

†This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Extra Strength Tylenol® PM.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS
BROKEN OR MISSING.**

Another Quality Product Distributed by McKesson

One Post Street, San Francisco, CA 94104

www.healthmart.com/healthmartbrand

Product Label

Exp. Date:
Lot No.:
FC0001162
PIL-DG



MCKESSON
 McKesson Quality Products Distributed by McKesson
 15000 E. Harvard Ave., Suite 200, Denver, CO 80231
 www.mckesson.com/harvard

Drug Facts (continued)
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Ask a doctor or pharmacist before use if you are
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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
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 ■ new symptoms occur
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Drug Facts (continued)
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 Diphenhydramine HCl 25 mg.....Nighttime sleep-aid
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NDC 62011-0197-1

compare to extra strength Tylenol® PM caplets active ingredients†

extra strength pain reliever pm

acetaminophen, 500 mg
 diphenhydramine HCl, 25 mg
 pain reliever/nighttime sleep-aid
 non-habit forming

actual size

50 caplets

Health Mart Pain Reliever PM Caplet

PAIN RELIEVER PM EXTRA STRENGTH			
acetaminophen, diphenhydramine hcl tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62011-0197
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
ALUMINUM OXIDE (UNII: LM26O6933)	

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:62011-0197-1	1 in 1 BOX	04/30/2013	12/31/2020
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	04/30/2013	12/31/2020

Labeler - McKesson (Health Mart) (177667227)

Registrant - P & L Development, LLC (800014821)

Revised: 12/2018

McKesson (Health Mart)