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 geltab)

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purposes

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

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

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
- if you have ever had an allergic reaction to this product or any of its ingredients

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 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 (1-800-22201222) 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 geltabs at bedtime. Do not take more than 2 geltabs of this product in 24 hours.
- children under 12 years: do not use

Other information

- store at room temperature 20°-25°C (68°-77°F)
- avoid high humidity and excessive heat

Inactive ingredients

corn starch, croscarmellose sodium*, D&C red #27 aluminum lake, edible black ink, FD&C blue #1 aluminum lake, gelatin, glycerin, hypromellose, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, purified water, silicon dioxide, sodium starch glycolate*, stearic acid, titanium dioxide

*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 the active ingredients in Extra Strength TYLENOL PM®†

EXTRA STRENGTH

Pain Reliever PM

ACETAMINOPHEN 500 mg,

Diphenhydramine HCl 25 mg

Pain reliever/Nighttime sleep-aid

Non-habit forming • For ages 12 years and over

GELTABS

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

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by McKesson

6555 State Highway 161 Irving, TX 75039

www.healthmart.com

Product Label

Exp. Date

Lot No.:

FC004871 PLD-630T



Distributed by McKesson 6555 State Highway 161 Irving, TX 75039 Money Back Guarantee ealthmart.com

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Orug Facts (continued)

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Other information

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cellulose, polyethylene glycol, povidone, purified water croscarmellose sodium*. D&C red #27 aluminum lake. edible black ink, FD&C blue #1 aluminum lake, gelatir glycerin, hypromellose, maltodextrin, microcrystalline silicon dioxide, sodium starch glycolate*, stearic acid, itanium dioxide

contains one or more of these ingredients

Questions or comments? Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Consumer Healthcare, distributor of Extra Strength Tylenol® PM. This product is not manufactured or distributed by McNei

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING. KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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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

sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious

underlying medical illness new symptoms occur

- pain gets worse or lasts more than 10 days redness or swelling is present
- 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

(eep out of reach of children. before use

or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well Overdose warning: In case of overdose, get medical help as for children even if you do not notice any signs or symptoms.

Diphenhydramine HCI 25 mg. Active ingredients in each geltab)

Purposes Nighttime sleep-aid

minor aches and pains with accompanying sleeplessness Temporary relief of occasional headaches and Uses

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skin reddening blisters rash

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Do not use

whether a drug contains acetaminophen, ask a doctor prescription or nonprescription). If you are not sure with any other drug containing acetaminophen or pharmacist

with any other product containing diphenhydramine,

■ in children under 12 years of age
■ if you have ever had an allergic reaction to this product or any of its ingredients even one used on skin

NDC 62011-0256-1

Compare to the active ingredients in Extra Strength Tylenol® PM†

EXTRA STRENGTH

Pain Relieve

Acetaminophen 500 mg Diphenhydramine HCl 25 mg

Pain reliever, Nighttime sleep-aid

Non habit-forming . For ages 12 years and over



ACTUAL SIZE

50 Geltabs

HEALTH MART Pain Reliever PM

PAIN RELIEVER PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl tablet, coated

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:62011-0256

Route of Administration ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PO VIDO NE (UNII: FZ989 GH94E)	
WATER (UNII: 059QF0KO0R)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
CROSCARMELLOSE SODIUM (UNII: M28 O L1HH48)	
ALUMINUM O XIDE (UNII: LMI26O6933)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics				
Color	WHITE, BLUE	Score	no score	
Shape	OVAL	Size	13mm	
Flavor		Imprint Code	BP50	
Contains				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date

1 NDC:62011-0256-	1 in 1 BOX	07/31/2015	
1	50 in 1 BOTTLE, PLASTIC; Type 0: No Product	ot a Combination	
Marketing Information			
Marketing Categ	ory Application Number or Mo	onograph Citation Marketing Start Date	Marketing End Date
OTC MONOGRAPH F	INAL part341	07/31/2015	

Labeler - McKesson (Health Mart) (177667227)

Revised: 6/2019 McKesson (Health Mart)