PAIN RELIEF PM EXTRA STRENGTH- acetaminophen, diphenhydramine hcl tablet, coated Good Sense (Geiss, Destin & Dunn, Inc.)

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 HCI 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

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 (1-800-222-1222) 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 20-25°C (68-86°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

Questions or comments?

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

Principal Display Panel Extra Strength

Pain Relief PM

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Nighttime Sleep Aid

Geltabs

Gluten Free

**Compare to Extra Strength Tylenol® PM active ingredients

**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:

Geiss, ddestin & dunn, inc.

Peachtree City, GA 30269

www.valuelabels.com

Product Label

^{*}contains one or more of these ingredients

Exp. Date

Lot No.:

PLD-D30S FC002798



Distributed by: Geiss, Destin & Dunn, Inc. Peachtree City, GA 30269

www.valuelabels.com

Orug Facts (continued)

- trouble urinating due to an enlarged prostate gland
 - daucoma

Purposes

Active ingredients

Drug Facts

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skin reddening

blisters

rash

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■ with other drugs containing acetaminophen

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**Compare to active i in Extra Strength Tylenol®PM

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NDC 50804-060-

liver disease bronchitis

Orug Facts (continued)

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nactive ingredients com starch

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

contains one or more of these ingredients

I-877-753-3935 Monday-Friday 9AM-5PM EST Questions or comments?

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

DO NOT USE IF PRINTED SAFETY SEAL TAMPER EVIDENT

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Diphenhydramine HCl 25 mg.

GOODSENSE «

Extra Strength

Relief

Acetaminophen 500 mg Diphenhydramine HCl 25 mg

Pain Reliever /Nighttime Sleep-Aid

50 Geltabs

Gluten Free

Good Sense Pain Relief PM Geltabs

PAIN RELIEF PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl tablet, coated

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50804-060

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: 08232NY3SJ)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ 989GH94E)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
ALUMINUM OXIDE (UNII: LMI2606933)	

Product Characteristics				
Color	white, blue	Score	no score	
Shape	ROUND	Size	13mm	

Flavor	Imprint Code	BP50
Contains		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50804- 060-50	1 in 1 BOX	08/31/2015	04/25/2025
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	08/31/2015	04/25/2025

Labeler - Good Sense (Geiss, Destin & Dunn, Inc.) (076059836)

Revised: 10/2022 Good Sense (Geiss, Destin & Dunn, Inc.)