

PAIN RELIEF PM EXTRA STRENGTH- acetaminophen and diphenhydramine hydrochloride tablet, coated
GoodSense

GDS - 1171 - 2022-0831

Drug Facts

Active ingredients (in each gelcap)	Purpose
Acetaminophen 500 mg	Pain reliever
Diphenhydramine HCl 25 mg	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 serious underlying medical illness.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

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	<ul style="list-style-type: none"> ▪ take 2 gelcaps at bedtime ▪ do not take more than 2 gelcaps of this product in 24 hours
children under 12 years	<ul style="list-style-type: none"> ▪ do not use

Other information

- store between 20-25°C (68-77°F)
- retain carton for complete product information

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, D&C red #28, D&C yellow #10, edible ink, FD&C blue #1, FD&C blue #2 aluminum lake, FD&C red #40, FD&C red #40

aluminum lake, FD&C yellow #6 aluminum lake, gelatin, hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, povidone, pregelatinized starch, stearic acid, titanium dioxide, triacetin

PRINCIPAL DISPLAY PANEL

GoodSense®

NDC 50804-825-02

Extra Strength

Pain Relief PM

For Adults

Actual Size

Acetaminophen, Diphenhydramine HCl

Pain Reliever/Nighttime Sleep-Aid

20 GELCAPS

Compare to active ingredients of Tylenol®PM†

INK AND COATING FREE
FOR LOT AND
EXPIRATION STAMPING

8 1152800 9509 4 8



F117101GBS_R1

DO NOT USE IF IMPRINTED SEAL
UNDER CAP IS BROKEN OR MISSING



Drug Facts

Active ingredients (in each gelcap) **Purpose**
Acetaminophen 500 mg..... Pain reliever
Diphenhydramine HCl 25 mg..... 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

Drug Facts (continued)

■ 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 ■ glaucoma
 ■ a breathing problem such as emphysema or chronic bronchitis
 ■ trouble urinating due to an enlarged prostate gland
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.
 ■ pain gets worse or lasts more than 10 days
 ■ fever gets worse or lasts more than 3 days
 ■ redness or swelling is present
 ■ new symptoms occur
 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.

Drug Facts (continued)

Directions ■ do not take more than directed (see overdose warning)

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children under 12 years	■ do not take more than 2 gelcaps of this product in 24 hours
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Other information

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

Distributed by:
Perrigo Direct, Inc.
Peachtree City, GA 30269
www.PerrigoDirect.com
1-844-705-4384
GoodSense® is a registered
trademark of L. Perrigo Company.
Made in India

GOODSENSE. NDC 50804-825-02

Extra Strength

Pain Relief PM For Adults
Actual Size

Acetaminophen, Diphenhydramine HCl
Pain Reliever / Nighttime Sleep Aid



20 GELCAPS

Compare to active ingredients of Tylenol® PM†

PAIN RELIEF PM EXTRA STRENGTH			
acetaminophen and diphenhydramine hydrochloride tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50804-825
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	gray (dark blue and light blue ends)	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	G3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50804-825-02	1 in 1 CARTON	08/01/2017	
1		20 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
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OTC Monograph Drug M013

08/01/2017

Labeler - GoodSense (076059836)

Revised: 10/2024

GoodSense