

**PAIN RELIEF PM EXTRA STRENGTH- acetaminophen, diphenhydramine hcl capsule, coated
HyVee 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.

Hy-Vee, Inc. Pain Relief PM Drug Facts

Active ingredient (in each gelcap)

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

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	do not use

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

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

See New Warnings

COMPARE TO the Active Ingredients of Extra Strength Tylenol® PM

Pain Relief PM

Pain Reliever / Nighttime Sleep Aid

Acetaminophen / Diphenhydramine HCl

Extra Strength

ACTUAL SIZE

For Adults

Non-Habit Forming

80 GELCAPS



Store at 20-25°C (68-77°F).

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

DISTRIBUTED BY HY-VEE, INC.
5820 WESTOWN PARKWAY
WEST DES MOINES, IA 50266
MADE IN INDIA

SATISFACTION GUARANTEED
OR PURCHASE PRICE REFUNDED
FOR INFORMATION CALL

1-800-289-8343
www.hy-vee.com

GLUTEN FREE

Drug Facts

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Diphenhydramine HCl 25 mg.....Nighttime sleep-aid

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Drug Facts (continued)

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Questions or comments? 1-800-719-9260

**DO NOT USE IF PRINTED SEAL UNDER CAP
IS BROKEN OR MISSING**

IS BROKEN OR MISSING



LOT NO.

EXP.

: 82927 2H C3

PAIN RELIEF PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl capsule, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42507-829
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)	
CROSCARMELOSE 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 RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONES (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	BLUE (Dark Blue Opaque) , GRAY, BLUE (Light Blue Opaque)	Score	no score
Shape	CAPSULE	Size	22mm
Flavor		Imprint Code	L829
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42507-829-27	1 in 1 CARTON		
1		80 in 1 BOTTLE		
2	NDC:42507-829-49	1 in 1 CARTON		
2		40 in 1 BOTTLE		
3	NDC:42507-829-60	1 in 1 CARTON		
3		20 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/02/2010	

Labeler - HyVee Inc (006925671)

Revised: 2/2015

HyVee Inc