PAIN RELIEF PM EXTRA STRENGTH- acetaminophen and diphenhydramine hydrochloride 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

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.

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 Liver warning)

adults and children 12 years and over	 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 this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

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?

1-800-719-9260

Package/Label Principal Display Panel

Compare to Extra Strength Tylenol® PM active ingredients

PAIN RELIEF PM

EXTRA STRENGTH

Pain Reliever

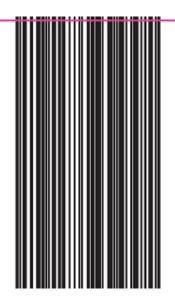
Night Time Sleep-Aid

Acetaminophen/Diphenhydramine HCl

Actual Size

Rapid Release







Pain Reliever • Night Time Sleep-Aid

40 GELCAPS

MIN RELIEF D

Compare to Extra Strength Tylenol® PI active ingredients* Drug Facts

NDC 42507-829-49

Store at 20°-25°C (68°-77°F).

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

Do not use in children under 12 years of age

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

Ask a doctor before use if you have

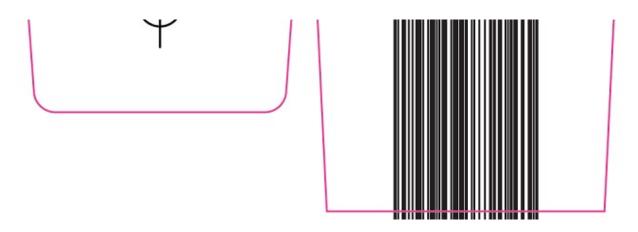
- liver disease
 glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

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PAIN RELIEF PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl capsule, coated

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Prod	nct	Into	rmation

Product TypeHUMAN OTC DRUG LABELItem Code (Source)NDC:42507-829

Route of Administration ORAL DEA Schedule

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINO PHEN (ACETAMINO PHEN)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE HYDRO CHLO RIDE (DIPHENHYDRAMINE)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients				
Ingredient Name	Strength			
SILICON DIO XIDE				
CROSCARMELLOSE SODIUM				
D&C RED NO. 28				
D&C YELLOW NO. 10				
FD&C BLUE NO. 1				
FD&C BLUE NO. 2				
FD&C YELLOW NO. 6				
FD&C RED NO. 40				
GELATIN				
HYDROXYPROPYL CELLULOSE (TYPE H)				
HYPROMELLOSES				
CELLULO SE, MICRO CRYSTALLINE				
POVIDONES				
STEARIC ACID				
TITANIUM DIO XIDE				
TRIACETIN				

Product Characteristics			
Color	BLUE (Dark Blue Opaque), GRAY, BLUE (Light Blue Opaque)	Score	no score

Shape	CAPSULE	Size	22mm
Flavor		Imprint Code	L829
Contains			

P	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 final	part338	08/02/2010	

Labeler - HyVee Inc (006925671)

Revised: 2/2013 HyVee Inc