HEADACHE PM FORMULA- acetaminophen and diphenhydramine hydrochloride tablet, film 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. Headache PM Formula Drug Facts

Active ingredient (in each tablet)

Acetaminophen 500 mg
Diphenhydramine HCl 25 mg
(equiv. to Diphenhydramine citrate 38 mg)

Purposes

Pain reliever

Nighttime sleep-aid

Uses

 for the 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
- 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

- avoid alcoholic drinks
- drowsiness may occur
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- sleeplessness lasts continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for 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 use more than directed (see Liver warning)

adults and children 12 years of age and over:

- take 2 tablets at bedtime, if needed, or as directed by a doctor
- do not take more than 2 tablets of this product in 24 hours

children under 12 years of age:

do not use

Other information

• store at 20-25°C (68-77°F)

Inactive ingredients

carnauba wax, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80,

povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

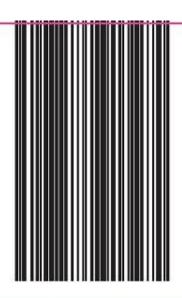
1-800-719-9260

Principal Display Panel

Diphenhydramine HCl

Compare to Excedrin® PM Tablets active ingredients
HEADACHE PM FORMULA
ADDED STRENGTH
Pain Reliever - Nighttime Sleep Aid
Acetaminophen





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Drug Facts (continued)

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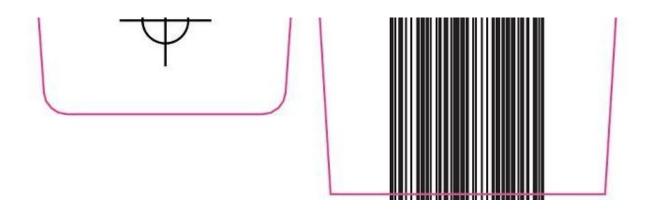
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HEADACHE PM FORMULA

acetaminophen, diphenhydramine hcl tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:42507-355	
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		
CARNAUBA WAX			
CROSPOVIDONE			
HYPROMELLOSES			
MAGNESIUM STEARATE			
CELLULO SE, MICRO CRYSTALLINE			
POLYETHYLENE GLYCOLS			
POLYSORBATE 80			
POVIDONES			
STEARIC ACID			
TITANIUM DIO XIDE			

Product Characteristics				
Color	BLUE	Score	no score	
Shape	ROUND (shallow convex)	Size	11mm	
Flavor		Imprint Code	L355;PM	
Contains				

Packaging

# It	em Code	Package Description	Marketin	g Start Date	Marke	ting End Date
1 NDC:425	07-355-71	1 in 1 CARTON				
1		50 in 1 BOTTLE				
Marketing Information						
Marketin	g Category	Application Number or Monogr	aph Citation	Marketing Start	Date Ma	rketing End Date

08/30/1998

Labeler - HyVee Inc (006925671)

part338

OTC monograph final

Revised: 1/2013 HyVee Inc