EQUALINE PAIN RELIEF PM- acetaminophen, diphenhydramine hcl tablet, coated Supervalu 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.

SuperValu Inc. Pain Relief PM Drug Facts

Active ingredient (in each geltab)

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

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

Ask a doctor or pharmacist before use if you are

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

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 lasts 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 geltabs at bedtime
- do not take more than 2 geltabs 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

Other information

• store at 20°-25°C (68°-77°F)

Inactive ingredients

crospovidone, D&C red no. 33, edetate disodium, edible ink, FD&C blue no. 1, gelatin, glycerin, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

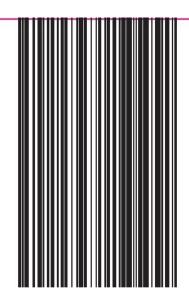
1-877-932-7948

Package/Label Principal Display Panel

compare to Extra Strength Tylenol® PM Geltabs active ingredients extra strength
pain relief PM
acetaminophen, diphenhydramine HCl
pain reliever/nighttime sleep aid
non-habit forming



Pain Relief PM Carton Image 1





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Phen, diphenhydramine HCl

see new warnings information

non-habit forming

compare to Extra Strength
Tylenol® PM Geltabs
active ingredients*

NDC 41163-837-71

Drug Facts

Active ingredients (in each geltab) Purpose

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Uses temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

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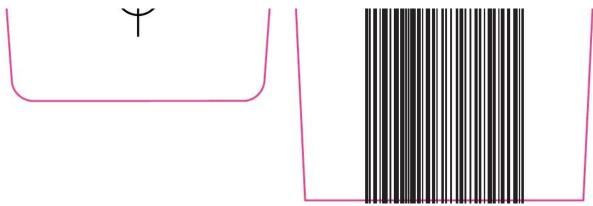
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Pain Relief PM Carton Image 2

EQUALINE PAIN RELIEF PM

acetaminophen, diphenhydramine hcl tablet, coated

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41163-837

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	500 mg		
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg		

Inactive Ingredients		
Ingredient Name	Strength	
CROSPO VIDO NE (UNII: 6840 1960 MK)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
PO VIDO NE (UNII: FZ989 GH94E)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)		

Product Characteristics				
Color	BLUE, WHITE	Score	no score	
Shape	ROUND (Convex)	Size	12mm	
Flavor		Imprint Code	L837	

Packaging # Item Code Package Description Marketing Start Date Marketing End Date

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part338	10/22/2004		

Labeler - Supervalu Inc (006961411)

1 in 1 CARTON

50 in 1 BOTTLE

Contains

1

1 NDC:41163-837-71

Revised: 12/2010 Supervalu Inc