# GOOD SENSE PAIN RELIEF PM EXTRA STRENGTH- acetaminophen, diphenhydramine hcl tablet, film coated

#### L. Perrigo Company

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.

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#### Perrigo Pain Relief PM Drug Facts

#### Active ingredients (in each caplet)

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

- 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

- new symptoms occur
- 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

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><li>take 2 caplets at bedtime</li><li>do not take more than 2 caplets of this product in 24 hours</li></ul>	
children under 12 years	do not use	

#### **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?

1-800-719-9260

### **Principal Display Panel**

See New Warnings

Extra Strength

Pain Relief PM CAPLETS

Pain Reliever/Nighttime Sleep-Aid

Acetaminophen

Diphenhydramine HCl

For Adults

**Actual Size** 

Compare to active ingredients of Tylenol® PM Caplets

50 Caplets

Non-Habit Forming



PD 20 T44Eh:

EXP.

LOT NO.



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Store at 20-25°C (68-77°F).

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## Drug Facts (continued)

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## GOOD SENSE PAIN RELIEF PM EXTRA STRENGTH

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Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0113-0437	
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	
<b>DIPHENHYDRAMINE HYDRO CHLO RIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg	

Inactive Ingredients		
Ingredient Name	Strength	
CARNAUBA WAX (UNII: R12CBM0EIZ)		
CROSPO VIDO NE (15 MPA.S AT 5%) (UNII: 68401960 MK)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POLYSORBATE 80 (UNII: 6 OZP39 ZG8 H)		
PO VIDO NE, UNSPECIFIED (UNII: FZ989GH94E)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

Product Characteristics			
Color	BLUE (Light blue)	Score	no score

Shape	CAPSULE	Size	18 mm
Flavor		Imprint Code	L437;PM
Contains			

Packaging				
# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1 NDC:0113-0437-71	1 in 1 CARTON	07/23/1992		
1	50 in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/23/1992	

## Labeler - L. Perrigo Company (006013346)

Revised: 12/2019 L. Perrigo Company