

**UNISOM PM PAIN NIGHTTIME SLEEP AID AND PAIN RELIEVER- acetaminophen and diphenhydramine hydrochloride tablet, film coated
Chattem, Inc.**

Unisom PM Pain Nighttime Sleep-Aid and Pain Reliever

Drug Facts

Active ingredients

(in each caplet)

Acetaminophen 325 mg

Purposes

Pain reliever

Active ingredients

(in each caplet)

Diphenhydramine HCl 50 mg

Purposes

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.
- in children under 12 years of age

- 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
- 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 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.

Overdose warning:

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. 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 older: • take 1 caplet at bedtime

- do not take more than 1 caplet 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

blue 1 lake, croscarmellose sodium, dicalcium phosphate, hydroxypropylcellulose, hypromellose, magnesium silicate, magnesium stearate, microcrystalline cellulose, mineral oil, pregelatinized corn starch, PVP, silica, sodium carboxymethyl starch, stearic acid (283-056)

PRINCIPAL DISPLAY PANEL

**Unisom®
PM PAIN
SLEEPCAPS™
30 Caplets**



UNISOM PM PAIN NIGHTTIME SLEEP AID AND PAIN RELIEVER
 acetaminophen and diphenhydramine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0040
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

Inactive Ingredients	
Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	white (White and blue)	Score	2 pieces
Shape	OVAL	Size	17mm
Flavor		Imprint Code	UNISOM;PM;PAIN
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0040-2	1 in 1 CARTON	12/01/2009	
1		15 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:41167-0040-3	1 in 1 CARTON	12/01/2009	04/10/2018
2		20 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:41167-0040-4	1 in 1 CARTON	12/01/2009	
3		30 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 Drug	M013	12/01/2009	

Labeler - Chattem, Inc. (003336013)

Revised: 10/2023

Chattem, Inc.