

**ACETAMINOPHEN PM EXTRA STRENGTH- acetaminophen, diphenhydramine hcl tablet, coated**

**BJWC (Berkley & Jensen / BJ's)**

*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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**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 accompanying sleeplessness.

**Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 2 caplets in 24 hours, which is the maximum daily amount
- 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 other products 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 a 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

**If pregnant or breast-feeding,**

ask a health care 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 (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 style="list-style-type: none"><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 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 room temperature 15°-30°C (59°-86°F), avoid high humidity and excessive heat

**Inactive ingredients**

colloidal silicon dioxide\*, croscarmellose sodium\*, D&C Yellow #10 Aluminum Lake\*, FD&C Blue #1 Aluminum Lake, FD&C Blue #2 Aluminum Lake, hypromellose, magnesium silicate\*, magnesium stearate\*, microcrystalline cellulose, mineral oil\*, polyethylene glycol, polyvinyl alcohol\*, povidone, pregelatinized starch, silica\*, sodium starch glycolate\*, stearic acid, talc\*, titanium dioxide, triacetin\*, and yellow iron oxide\*

\*contains one or more of these ingredients

**Questions or comments?**

Call toll free: **1-800-934-1204 Monday-Friday 9AM-5PM EST**

**Principal Display Panel**

PAIN RELIEVER/NIGHTTIME SLEEP-AID

EXTRA STRENGTH

NON-ASPIRIN PM

**ACETAMINOPHEN 500 mg**

DIPHENHYDRAMINE HCl 25 mg

Compare to the active ingredients of Tylenol® PM Caplets\*\*

CAPLETS

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

\*\*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol® PM.

Distributed by BJWC

25 Research Drive

Westborough, MA 01581

1-800-934-1204

### Package Label

**BERKLEY & JENSEN®** PAIN RELIEVER/NIGHTTIME SLEEP-AID

EXTRA STRENGTH  
**NON-ASPIRIN PM**  
**ACETAMINOPHEN 500 mg**  
DIPHENHYDRAMINE HCl 25 mg

Compare to the active ingredients of Tylenol® PM Caplets\*\*

**500 CAPLETS**

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**Drug Facts**

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- Acetaminophen 500 mg..... Pain reliever
- Diphenhydramine HCl 25 mg..... Nighttime sleep-aid

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**Drug Facts (continued under label)**

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**Quality Guaranteed**

Distributed by BJWC  
25 Research Drive  
Westborough, MA 01581  
1-800-934-1204

PLD-A  
LB000783  
Lot No.:  
Exp. Date:

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**PEEL HERE**

**Drug Facts (continued)**

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**Directions** ■ do not take more than directed (see overdose warning)

adults and children 12 years and over	■ take 2 caplets at bedtime
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BERKLEY & JENSEN EXTRA STRENGTH NON-ASPIRIN PM CAPLETS

ACETAMINOPHEN PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl tablet, coated

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68391-161
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

## Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POVIDONES (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	
ALUMINUM OXIDE (UNII: LM26O6933)	
MINERAL OIL (UNII: T5L8T28FGP)	
STARCH, CORN (UNII: O8232NY3SJ)	
TRIACETIN (UNII: XHX3C3X673)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

## Product Characteristics

Color	BLUE	Score	no score
Shape	CAPSULE	Size	7mm
Flavor		Imprint Code	S525;CPC752
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68391-161-05	500 in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	01/15/2013	

**Labeler** - BJWC (Berkley & Jensen / BJ's) (159082692)

**Registrant** - P and L Development of New York Corporation (800014821)

Revised: 12/2012

BJWC (Berkley & Jensen / BJ's)