# PAIN RELIEVER PM EXTRA STRENGTH- acetaminophen, diphenhydramine hcl tablet, coated BJWC (Berkley & Jensen / BJ's)

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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 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

- 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
- 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.
- new symptoms occur

- redness or swelling is present
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days

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 (1-800-222-1222) 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 over: take 2 caplets at bedtime. Do not take more than 2 caplets of this product in 24 hours.
- children under 12 years: do not use

#### Other information

- store between 20-25°C (68-77°F)
- · avoid high humidity and excessive heat

## **Inactive ingredients**

croscarmellose sodium, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone K30, pregelatinized starch, purified water, silicon dioxide, sodium starch glycolate, talc, titanium dioxide

## **Questions or comments?**

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

#### **Principal Display Panel**

Compare to the active ingredients in Extra Strength Tylenol® PM<sup>†</sup>

**EXTRA STRENGTH** 

PAIN RELIEVER PM

ACETAMINOPHEN 500 mg

DIPHENHYDRAMINE HCl 25 mg

PAIN RELIEVER/NIGHTTIME SLEEP-AID

NON HABIT-FORMING

FOR AGES 12+

**CAPLETS** 

<sup>†</sup>This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Extra Strength Tylenol® PM.

#### TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Distributed by: BJ's Wholesale Club

25 Research Drive

Westborough, MA 01581

Questions? 1-800-934-1204

## BERKLEY JENSEN (BJs) Extra Strength Pain Reliever PM

## PAIN RELIEVER PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl tablet, coated

## **Product Information**

HUMAN OTC DRUG **Product Type** NDC:68391-863 Item Code (Source)

**Route of Administration** ORAL

## Active Ingredient/Active Moiety

Active ingredient/Active Profesy		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

## **Inactive Ingredients**

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
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 GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
WATER (UNII: 059QF0KOOR)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2 P)	

## **Product Characteristics**

Color	blue	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	P525
Contains			

## **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68391-863-05	500 in 1 ROTTLE PLASTIC: Type 0: Not a Combination Product	11/29/2019	

## Marketing Information

Marketing Category	<b>Application Number or Monograph Citation</b>	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M013	11/29/2019		

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

Revised: 2/2024

BJWC (Berkley & Jensen / BJ's)