

**ACETAMINOPHEN PM EXTRA STRENGTH- acetaminophen, diphenhydramine  
hcl tablet, coated  
CHAIN DRUG MARKETING ASSOCIATION INC**

-----  
**Quality Choice 44-556 Delisted**

***Active ingredients (in each gelcap)***

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
- difficulty in urination due to enlargement of the 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 beverages
- 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.**

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt 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**
- adults and children 12 years and over
  - take 2 gelcaps at bedtime
  - do not take more than 2 gelcaps of this product in 24 hours
- children under 12 years: do not use

***Other information***

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid high humidity
- see end flap for expiration date and lot number

***Inactive ingredients***

ammonium hydroxide, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1,

FD&C red #3, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, simethicone, stearic acid, titanium dioxide

**Questions or comments?**

**1-800-426-9391**

**Principal Display Panel**

**QC<sup>®</sup>  
QUALITY  
CHOICE**

NDC 63868-210-20

Compare to the active ingredients  
in EXTRA STRENGTH  
TYLENOL<sup>®</sup> PM\*

**Extra Strength  
Acetaminophen PM**

**Acetaminophen** 500 mg,  
Diphenhydramine HCl 25 mg  
Pain Reliever / Nighttime Sleep-Aid

**20** Gelcaps

Non-Habit Forming

Actual Size

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED  
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

\*This product is not manufactured or distributed by  
Johnson & Johnson Corporation, owner of the registered  
trademark Extra Strength Tylenol<sup>®</sup> PM.

50844 REV0322C55609

Distributed by CDMA, Inc.

Novi, MI 48375

[www.qualitychoice.com](http://www.qualitychoice.com)

Questions: 800-935-2362

# ACETAMINOPHEN PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-210

**No Print / No Varnish**  
Lot no. & Exp. date

**QC**  
QUALITY CHOICE

NDC 63868-210-20

Compare to the active ingredients  
in EXTRA STRENGTH  
**TYLENOL® PM\***

**Extra Strength**  
**Acetaminophen PM**  
**Acetaminophen 500 mg,**  
**Diphenhydramine HCl 25 mg**  
Pain Reliever / Nighttime Sleep-Aid



**20** Gelcaps

Non-Habit Forming

Actual Size

TAMPER EVIDENT: DO NOT USE IF IMPRINTED  
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

B-0220-556-09  
REV0322C55609

**Drug Facts (continued)**

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. Prompt 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
- adults and children 12 years and over
- take 2 gelcaps at bedtime
- do not take more than 2 gelcaps of this product in 24 hours
- children under 12 years: do not use

**Other information**

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid high humidity
- see end flap for expiration date and lot number

**Inactive ingredients** ammonium hydroxide, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1, FD&C red #3, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized

**Drug Facts (continued)**

- 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
- difficulty in urination due to enlargement of the 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 beverages
- do not drive a motor vehicle or operate machinery

**Stop use and ask a doctor if**

- sleepiness 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.

**Drug Facts (continued)**

starch, propylene glycol, shellac glaze, simethicone, stearic acid, titanium dioxide

**Questions or comments?**  
1-800-426-9391

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Extra Strength Tylenol® PM.  
50844 REV0322C55609

Distributed by CDMA, Inc.  
Norri, RI 04875  
www.qualitychoice.com  
Questions: 800-935-2362

**Drug Facts**

**Active ingredients (in each gelcap)**

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

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

**Warnings**  
**Liver warnings:** 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.

**KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION**

**Quality Choice 44-556**

Route of Administration ORAL

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 3</b> (UNII: PN2ZH5LOQY)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 9XZ8H6N6OH)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B710)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	blue (dark) , blue (light)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	L;6
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-210-20	1 in 1 CARTON	12/17/2007	12/31/2026
1		20 in 1 BOTTLE, PLASTIC; 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	12/17/2007	12/31/2026

**Labeler** - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	manufacture(63868-210) , pack(63868-210)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(63868-210)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(63868-210)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(63868-210)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(63868-210)

Revised: 10/2025

CHAIN DRUG MARKETING ASSOCIATION INC