

**ACETAMINOPHEN PM- acetaminophen, diphenhydramine hcl tablet, coated**  
**COSTCO WHOLESALE CORPORATION**

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**Kirkland 44-556-Acetaminophen PM**

***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.
- 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
- glaucoma

- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland

**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 beverages
- do not drive a motor vehicle or operate machinery

**Stop use and ask a doctor if**

- new symptoms occur
- redness or swelling is present
- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.
- 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***

- use by expiration date on package
- avoid high humidity
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

***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**

**KIRKLAND**

*Signature*

**COMPARE TO EXTRA  
STRENGTH TYLENOL® PM**

*active ingredients\**

NDC 63981-056-54

ITM. / ART. 596759

**EXTRA STRENGTH  
ACETAMINOPHEN PM  
GELCAPS**

**Acetaminophen 500 mg**

*Diphenhydramine HCl 25 mg*

*Pain Reliever • Nighttime Sleep Aid*

*Non-Habit Forming*

*Temporarily Relieves:*

- *Headache*
- *Minor Aches and Pains Accompanied by Sleeplessness*

*Actual*

*Size*

*375*

*Gelcaps*

**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® PM. 50844  
REV0322L55654

Manufactured by: LNK INTERNATIONAL, INC.  
60 Arkay Drive, Hauppauge, NY 11788 USA  
Distributed by: Costco Wholesale Corporation  
999 Lake Drive, Issaquah, WA 98027 USA

No print/No varnish area  
Lot no/Exp date

**Drug Facts (continued)**

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

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: new symptoms occur; redness or swelling is present; sleeplessness persists continuously for more than 2 weeks; Insomnia may be a symptom of a serious underlying medical illness; 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** use by expiration date on package; avoid high humidity; store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

**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

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COMPARE TO EXTRA STRENGTH TYLENOL® PM active ingredients\*

NDC 63981-056-54  
ITM. / ART. 596759

# EXTRA STRENGTH ACETAMINOPHEN GELCAPS PM

Acetaminophen 500 mg  
Diphenhydramine HCl 25 mg

Pain Reliever • Nighttime Sleep Aid

Non-Habit Forming  
Temporarily Relieves:  
Headache  
Minor Aches and Pains Accompanied by Sleeplessness



375 Gelcaps

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

**Active ingredients (in each gelcap)**

Active ingredients (in each gelcap)	Purpose
Acetaminophen 500 mg	Pain reliever
Diphenhydramine HCl 25 mg	Nighttime sleep-aid

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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; 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; glaucoma; a breathing problem such as emphysema or chronic bronchitis; difficulty in urination due to enlargement of the prostate gland

0 96619 59675 1

Manufactured by LNK INTERNATIONAL, INC. 60 Arkey Drive, Hauppauge, NY 11788 USA  
Distributed by: Costco Wholesale Corporation 999 Lake Drive, Issaquah, WA 98027 USA  
www.costco.com 22V13037a

Kirkland 44-556

## ACETAMINOPHEN PM

acetaminophen, diphenhydramine hcl tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63981-056
<b>Route of Administration</b>	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>CROSCARMELOSE 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>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX43802MRT)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

**POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E)

**STARCH, CORN** (UNII: O8232NY3SJ)

**PROPYLENE GLYCOL** (UNII: 6DC9Q167V3)

**SHELLAC** (UNII: 46N107B71O)

**STEARIC ACID** (UNII: 4ELV7Z65AP)

**TITANIUM DIOXIDE** (UNII: 15FIX9V2JP)

### Product Characteristics

<b>Color</b>	blue (dark blue) , blue (light blue)	<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:63981-056-54	375 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/04/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	10/04/2022	

**Labeler** - COSTCO WHOLESALE CORPORATION (103391843)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	manufacture(63981-056) , pack(63981-056)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(63981-056)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(63981-056)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(63981-056)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		967626305	pack(63981-056)

Revised: 8/2023

COSTCO WHOLESALE CORPORATION