

**RAPID RELEASE ACETAMINOPHEN PM EXTRA STRENGTH- acetaminophen and diphenhydramine hcl tablet, coated
COSTCO WHOLESALE CORPORATION**

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.

Kirkland 44-556-Rapid Release 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.
- in children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin

- if you are allergic to acetaminophen or any of the inactive ingredients in this product

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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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°C-30°C (59°F-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 63981-556-54

ITM./ART. 596759

EXTRA STRENGTH

RAPID RELEASE

ACETAMINOPHEN 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

Actual Size

375

Rapid Release Gelcaps

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

Manufactured by: LNK INTERNATIONAL, INC.

60 Arkay Drive, Hauppauge, NY 11788 USA

For: Costco Wholesale Corporation

P.O. Box 34535, Seattle, WA 98124-1535 USA

1-800-774-2678 www.costco.com 17V0218a

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

This product does not contain gluten.

KIRKLAND Signature
EXTRA STRENGTH RAPID RELEASE ACETAMINOPHEN
 Acetaminophen 500 mg PM
 Diphenhydramine HCl 25 mg
 Pain Reliever • Nighttime Sleep Aid
 375 Rapid Release Gelcaps

Drug Facts (continued)
 Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers or 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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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? 1-800-428-9391
 This product does not contain gluten.

Drug Facts
 TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.
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 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 are allergic to acetaminophen or any of the inactive ingredients in this product.
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.
 *This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Extra Strength Tylenol® PM, 50844 REV0417J55654

Kirkland 44-556

RAPID RELEASE ACETAMINOPHEN PM EXTRA STRENGTH			
acetaminophen and diphenhydramine hcl tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63981-556
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
AMMONIA (UNII: 5138Q19F1X)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)			
GELATIN (UNII: 2G86QN327L)			
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
FERROSO FERRIC OXIDE (UNII: XM0M87F357)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)			

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
POVIDONE (UNII: FZ989GH94E)
STARCH, CORN (UNII: O8232NY3SJ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHELLAC (UNII: 46N107B71O)
DIMETHICONE (UNII: 92RU3N3Y1O)
STEARIC ACID (UNII: 4ELV7Z65AP)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	blue (Dark) , blue (Light)	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	L;6
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63981-556-54	375 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/17/2007	10/27/2024
2	NDC:63981-556-24	1 in 1 CARTON	12/17/2007	10/01/2021
2		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/17/2007	10/27/2024

Labeler - COSTCO WHOLESALE CORPORATION (103391843)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(63981-556)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(63981-556)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(63981-556) , pack(63981-556)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(63981-556)

Revised: 11/2022

COSTCO WHOLESALE CORPORATION