PAIN RELIEF PM EXTRA STRENGTH- acetaminophen, diphenhydramine hcl tablet, coated H E B

HEB 44-556

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

a breathing problem such as emphysema or chronic bronchitis

- difficulty in urination due to enlargement of the prostate gland
- glaucoma
- liver disease

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
- use by expiration date on package

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

Compare to Tylenol[®] PM Extra Strength active ingredients*

NDC 37808-556-31

H•E•B ® Extra Strength PAIN RELIEF PM

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

•Non-Habit Forming

actual size

80 GELCAPS

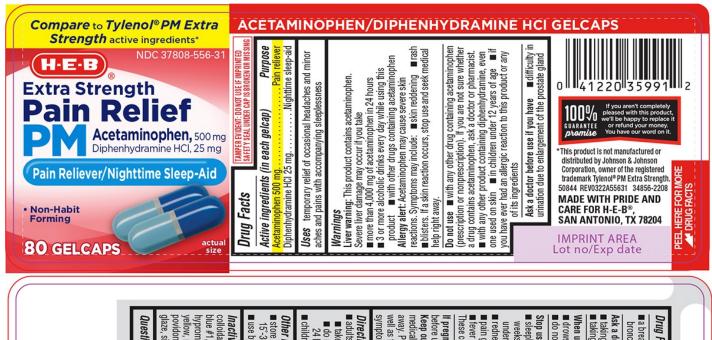
*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Tylenol® PM Extra Strength. 50844 REV0322A55631 34856-2208

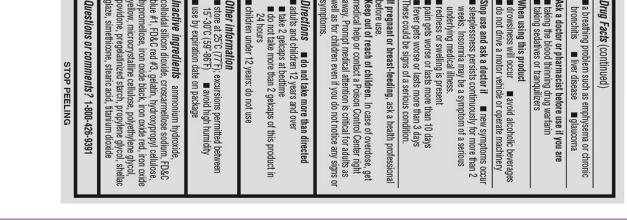
TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

MADE WITH PRIDE AND CARE FOR H-E-B®, SAN ANTONIO, TX 78204

100% GUARANTEE promise

If you aren't completely pleased with this product, we'll be happy to replace it or refund your money. You have our word on it.







PAIN RELIEF PM EXTRA STRENGTH acetaminophen, diphenhydramine hcl tablet, coated **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:37808-556 **Route of Administration** ORAL Active Ingredient/Active Moiety **Ingredient Name Basis of Strength** Strength ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN 500 mg DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) DIPHENHYDRAMINE 25 mg (DIPHENHYDRAMINE - UNII:8GTS82S83M) **HYDROCHLORIDE Inactive Ingredients Ingredient Name** Strength **AMMONIA** (UNII: 5138Q19F1X)

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQOSDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: 08232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B710)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808- 556-09	1 in 1 CARTON 12/17/2007		
1		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:37808- 556-31	80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/17/2007	
Marketing Information				
	Marketing Category	Application Number or Monograph	Marketing Start	Marketing End

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	12/17/2007	

Labeler - H E B (007924756)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	manufacture(37808-556) , pack(37808-556)

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		832867837	manufacture(37808-556)	
Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		832867894	manufacture(37808-556)	
Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		868734088	manufacture(37808-556)	
Establishment				
Name	Address	ID/FEI	Business Operations	

967626305

pack(37808-556)

Revised: 9/2023

LNK International, Inc.

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