PAIN RELIEVER PM EXTRA STRENGTH- acetaminophen and diphenhydramine hydrochloride capsule
H E B

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.

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

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

Ask a doctor before use if you have
- a breathing problem such as emphysema or chronic bronchitis
- liver disease
- glaucoma
- trouble urinating due to an enlarged prostate gland

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

When using this product
- avoid alcoholic beverages
- drowsiness will occur
- 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: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center 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 gelcaps at bedtime
  - do not take more than 2 gelcaps of this product in 24 hours
- children under 12 years: do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage.

Other information

- store at 25ºC (77ºF); ecursions permitted between 15º-30ºC (59º-86ºF)
- 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, pregelatinied starch, propylene gllycol, shellac glaze, stearic acid, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

Compare to Extra Strength Tylenol® PM Rapid Release Gels active ingredients*

NDC 37808-556-09

H-E-B®
PAIN RELIEF PM
Extra Strength • Rapid Release
Acetaminophen, Diphenhydramine HCl

Pain Reliever/Nighttime Sleep-Aid
Non-Habit Forming

20 Gelcaps

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Extra Strength Tylenol® PM Rapid Release Gels.
50844 ORG071255609 1212

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

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

HEB 44-556

PAIN RELIEVER PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:37808-556
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (ACETAMINOPHEN)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE HYDROCHLORIDE (DIPHENHYDRAMINE)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE	
CROSCARMELLOSE SODIUM	
FD&C BLUE NO. 1	
FD&C RED NO. 3	
HYDROXYPROPYL CELLULOSE (TYPE H)	
HYPROMELLOSES	
POLYETHYLENE GLYCOLS	
PROPYLENE GLYCOL	
STEARIC ACID	
TITANIUM DIOXIDE	

Product Characteristics

Color	BLUE	**Score**	no score
Shape	CAPSULE	**Size**	21mm
Flavor		**Imprint Code**	L;6
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-556-09	1 in 1 CARTON		
1		20 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part341	12/17/2007	

Labeler - HEB (007924756)

Establishment

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

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(37808-556)