PAIN RELIEF PM EXTRA STRENGTH- acetaminophen, diphenhydramine hcl tablet
CVS Pharmacy

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.

CVS 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:

- with other drugs containing acetaminophen
- more than 4,000 mg of acetaminophen in 24 hours
- 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
- if you are allergic to acetaminophen or any of the inactive ingredients in this product
- in children under 12 years of age

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

- pain gets worse or lasts more than 10 days
- 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
- 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

- avoid high humidity
- store at 25ºC (77ºF); excursions permitted between 15°-30°C (59°-86°F)
- 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

CVS
Health™

Compare to the active ingredients
in Extra Strength Tylenol® PM*

Gelcaps
NDC 59779-556-13

EXTRA STRENGTH
Pain Relief PM

ACETAMINOPHEN, 500 mg
DIPHENHYDRAMINE HCl, 25 mg

Pain reliever,
Nighttime sleep aid

Non-habit forming

Actual Size RAPID RELEASE

250 GELCAPS

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

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Extra Strength Tylenol® PM.
50844 ORG061555613

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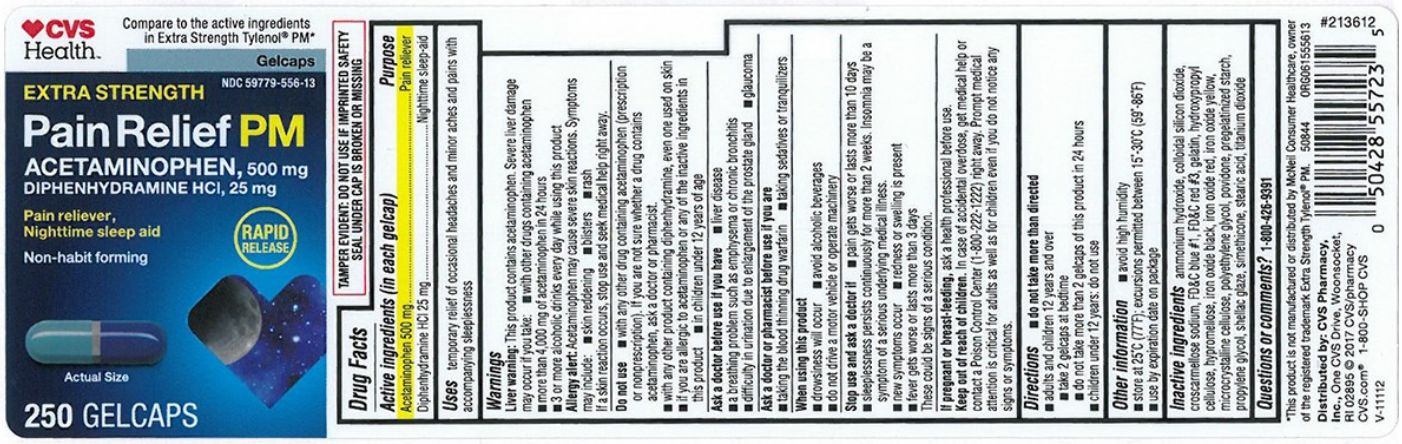

CVS 44-556

PAIN RELIEF PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59779-556

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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE 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)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
AMMONIA (UNII: 5138Q19F1X)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
STARCH, CORN (UNII: O8232NY3SJ)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics

Color	BLUE (dark blue) , BLUE (light blue)	**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:59779-556-31	1 in 1 CARTON	12/17/2007	01/08/2023
1		80 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:59779-556-09	1 in 1 CARTON	12/17/2007	01/08/2023
2		20 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:59779-556-13	250 in 1 BOTTLE; Type 0: Not a Combination Product	12/17/2007	11/16/2020
4	NDC:59779-556-76	450 in 1 BOTTLE; Type 0: Not a Combination Product	12/17/2017	08/18/2018

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	12/17/2007	01/08/2023

Labeler - CVS Pharmacy (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(59779-556)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	MANUFACTURE(59779-556) , PACK(59779-556)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(59779-556)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(59779-556)