EXTRA STRENGTH PAIN RELIEVER PM- acetaminophen and diphenhydramine hydrochloride capsule Safeway

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.

Safeway 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

- liver disease
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- 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

- drowsiness will occur
- aboid alcoholic beverages
- do not drive a motor vehicle or operate machiner

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 controlled room temperature 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

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

NDC 21130-556-31

Compare to Extra Strength Tylenol® PM active ingredients*

Extra Strength

Pain Reliever PM Acetaminophen, 500 mg

Diphenhydramine HCL, 25 mg

- Rapid Release Gels
- Pain Reliever/Nighttime Sleep Aid

SEE NEW WARNINGS

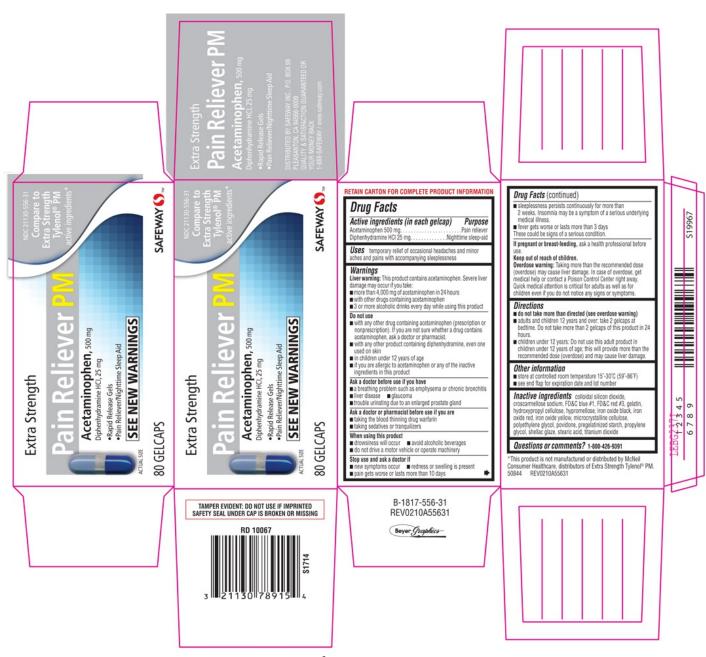
80 GELCAPS

SAFEWAYTM

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

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



Safeway 44-556

EXTRA STRENGTH PAIN RELIEVER PM

acetaminophen and diphenhydramine hcl capsule

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:21130-556
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINO PHEN (ACETAMINO PHEN)	ACETAMINOPHEN	500 mg		
DIPHENHYDRAMINE HYDRO CHLO RIDE (DIPHENHYDRAMINE)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg		

Inactive Ingredients				
Ingredient Name	Strength			
SILICON DIO XIDE				
CROSCARMELLOSE SODIUM				
FD&C BLUE NO. 1				
FD&C RED NO. 3				
HYDRO XYPRO PYL CELLULO SE (TYPE H)				
HYPROMELLOSES				
POLYETHYLENE GLYCOLS				
PROPYLENE GLYCOL				
STEARIC ACID				
TITANIUM DIO XIDE				

olor BLUE			
		Score	no score
hap e CAPSUL	ĿΕ	Size	21mm
lavor		Imprint Code	L;6
ontains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-556-31	1 in 1 CARTON		
1		80 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 - Safeway (009137209)

Establishment			
Name	Address	ID/FEI	Business Operations

LNK International, Inc. 038154464 PACK(21130-556)	
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Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		832867894	MANUFACTURE(21130-556)	

Revised: 10/2012 Safeway