PAIN RELIEF PM EXTRA STRENGTH- acetaminophen and diphenhydramine hydrochloride tablet SuperValu (Equaline)

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.

DRUG FACTS

Active ingredients (in each caplet)

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purpose

Pain reliever

Nighttime sleep-aid

Uses

Temporary relief of occasional headaches and minor aches and pains 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 products containing diphenhydramine, even one used on skin
- 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
- trouble urinating due to an enlarged 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 drinks
- 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 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 care professional before use.

Keep out of reach of children.

Overdose warning: 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 caplets at bedtime. Do not take more than 2 caplets of this product in 24 hours.
- children under 12 years: do not use

Other information

- store at room temperature 15°- 30° C (59°- 86° F)
- avoid high humidity and excessive heat

Inactive ingredients

croscarmellose sodium*, D&C Yellow #10 Aluminum Lake*, FD&C Blue #1 Aluminum Lake, FD&C Blue #2 Aluminum Lake*, hypromellose, magnesium silicate*, magnesium stearate*, microcrystalline cellulose*, mineral oil*, polyethylene glycol*, povidone, pregelatinized starch, silica*, sodium starch glycolate*, stearic acid, talc*, titanium dioxide, triacetin*

Questions or comments?

Call toll free 1-877-932-7948

Principal Display Panel

Compare to Extra Strength TYLENOL® PM Caplets active ingredients** extra strength

Pain Relief PM

ACETAMINOPHEN 500 mg

DIPHENHYDRAMINE HCl 25 mg

Pain reliever/ Nighttime Sleep Aid

Non Habit forming

^{*}contains one or more of these ingredients

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Product Label



PAIN RELIEF PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl tablet

Product Information				
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:41163-214	
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
CROSCARMELLOSE SODIUM	
D&C YELLOW NO. 10	
FD&C BLUE NO. 1	
FD&C BLUE NO. 2	
HYPROMELLOSES	
MAGNESIUM SILICATE	
MAGNESIUM STEARATE	
CELLULO SE, MICRO CRYSTALLINE	
MINERAL OIL	
POLYETHYLENE GLYCOLS	
POVIDONES	
STARCH, CORN	
SILICON DIO XIDE	
SO DIUM STARCH GLYCOLATE TYPE A CORN	
STEARIC ACID	
TITANIUM DIO XIDE	
TRIACETIN	
ALUMINUM O XIDE	

Product Characteristics				
Color	BLUE	Score	no score	
Shape	CAPSULE	Size	18 mm	
Flavor		Imprint Code	S525;CPC752	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:41163-214-10	1 in 1 BOX			
1		100 in 1 BOTTLE			
2	NDC:41163-214-50	1 in 1 BOX			

2	50 in 1 BOTTLE			
B.C. 1 . T.C.	.•			
Marketing Information				
Marketing Category	Application Number or Monogr	aph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part338		03/25/2013	

Labeler - SuperValu (Equaline) (006961411)

Registrant - P and L Development of New York Corporation (800014821)

Revised: 2/2013 SuperValu (Equaline)