NON ASPIRIN PM EXTRA STRENGTH- acetaminophen, diphenhydramine hcl tablet, coated
Freds Inc

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 geltab)

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

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

Other information

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

Inactive ingredients

corn starch*, croscarmellose sodium*, D&C red #27 aluminum lake, edible black ink, FD&C blue #1 aluminum lake, gelatin, glycerin, hypromellose*, maltodextrin*, microcrystalline cellulose*, polyethylene glycol*, povidone*, purified water, silicon dioxide*, stearic acid, titanium dioxide
*contains one or more of these ingredients

Questions or comments?

Call toll free **1-877-753-3935 Monday- Friday 9AM- 5PM EST**

Principal Display Panel

Compare to the active ingredients in extra strength TYLENOL® PM **

NON-ASPIRIN PM

extra strength

ACETAMINOPHEN 500 mg

DIPHENHYDRAMINE HCl 25 mg

pain reliever/ nighttime sleep-aid

****** 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

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

Product Label

Non-Aspirin PM Geltabs

NON ASPIRIN PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55315-360
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**
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WQ0SDW1A)	
POVIDONES (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

Product Characteristics			
Color	BLUE, WHITE	**Score**	no score
Shape	ROUND	**Size**	13mm
Flavor		**Imprint Code**	BPI50
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55315-360-10	1 in 1 CARTON		
1		100 in 1 BOTTLE		
2	NDC:55315-360-50	1 in 1 CARTON		
2		50 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part338	11/30/2012	

Labeler - Freds Inc (005866116)

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

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