# NON ASPIRIN PM EXTRA STRENGTH- acetaminophen and diphenhydramine hydrochloride 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.

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#### **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 15°- 30° C (59°- 86° 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 EXTRA STRENGTH

acetaminophen, diphenhydramine hcl tablet, coated

Route of Administration ORAL DEA Schedule

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINO PHEN (ACETAMINO PHEN)	ACETAMINOPHEN	500 mg
<b>DIPHENHYDRAMINE HYDRO CHLO RIDE</b> (DIPHENHYDRAMINE)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

## **Inactive Ingredients**

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Ingredient Name	Strength	
STARCH, CORN		
CROSCARMELLOSE SODIUM		
D&C RED NO. 27		
FD&C BLUE NO. 1		
GELATIN		
GLYCERIN		
HYPROMELLOSES		
MALTO DEXTRIN		
CELLULO SE, MICRO CRYSTALLINE		
POLYETHYLENE GLYCOLS		
POVIDONES		
WATER		
SILICON DIO XIDE		
STEARIC ACID		
TITANIUM DIO XIDE		
ALUMINUM O XIDE		

## **Product Characteristics**

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

## Packaging

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)

Revised: 12/2012 Freds Inc