

**ACETAMINOPHEN PM EXTRA STRENGTH- acetaminophen, diphenhydramine  
hcl tablet, coated**  
**United Natural Foods, Inc. dba UNFI**

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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

**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
- in children under 12 years of age
- if you have ever had an allergic reaction to this product or any of its ingredients

**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 (1-800-222-1222) 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 gels at bedtime. Do not take more than 2 gels of this product in 24 hours.
- children under 12 years: do not use

**Other information**

- store between 20-25°C (68-77°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

### **Questions or comments?**

Call toll free **1-855-423-2630**

### **Principal Display Panel**

Compare to Extra Strength Tylenol® PM active ingredients†

Extra Strength

#### **Acetaminophen PM**

#### **Acetaminophen 500 mg**

Diphenhydramine HCl 25 mg

Pain reliever/nighttime sleep-aid

Non-habit Forming

Geltabs

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Extra Strength Tylenol® PM.

DISTRIBUTED BY UNFI, PROVIDENCE, RI 02908 USA

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**

### **Product Label**

EQUALINE®

extra strength  
**acetaminophen PM**  
**acetaminophen 500mg**  
diphenhydramine HCl 25mg  
pain reliever/nighttime sleep-aid  
non habit-forming

**50**geltabs

compare to Extra  
Strength Tylenol® PM  
active ingredients\*  
NDC 41163-228-50



actual size

### Drug Facts

#### Active ingredients (in each geltab)

Acetaminophen 500 mg.....Pain reliever  
Diphenhydramine HCl 25 mg.....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

**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  
■ in children under 12 years of age  
■ if you have ever had an allergic reaction to this product or any of its ingredients

### Drug Facts (continued)

#### 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 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:** In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### Drug Facts (continued)

#### 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 between 20-25°C (68-77°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

#### Questions or comments?

Call toll free 1-855-423-2630

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Extra Strength Tylenol® PM.

**GLUTEN FREE**

DISTRIBUTED BY UNFI, PROVIDENCE, RI 02908 USA

Like it or let us make it right.  
That's our quality promise.  
855-423-2630

**100% Quality  
GUARANTEED**

Exp. Date:

Lot No.:

FC003364

PLD-G30U

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KEEP OUTER CARTON FOR COMPLETE  
WARNINGS AND PRODUCT INFORMATION.

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

EQUALINE Extra Strength Acetaminophen PM Geltabs

ACETAMINOPHEN PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-228
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name		Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		500 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)		25 mg

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
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 GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

Product Characteristics			
Color	white, blue	Score	no score
Shape	ROUND	Size	13mm
Flavor		Imprint Code	BP50
Contains			

Packaging			
		Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-228-50	1 in 1 BOX	08/29/2014	
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	08/29/2014	

**Labeler -**
United Natural Foods, Inc. dba UNFI (943556183)