

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

Drug Facts

Active ingredients (in each geltaab)

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

Geltabs

GLUTEN FREE

*This product is not manufactured or distributed by Kenvue Brands LLC., distributor of Extra Strength Tylenol® PM.

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY UNFI, PROVIDENCE, RI 02908 USA

Product Label

Exp. Date:
Lot No.:
FC009361
P.D.-H30V



KEEP OUTER CARTON FOR COMPLET
WARNINGS AND PRODUCT INFORMATION.
TAMPER EVIDENT, DO NOT USE IF PRINTED SAFETY
SEAL UNDER CAP IS BROKEN OR MISSING.

50 geltabs
pain reliever/nighttime sleep-aid
diphenhydramine HCl 25mg
acetaminophen 500mg
extra strength
EQUALINE
compare to Extra
Strength Tylenol[®] PM
active ingredients
NDC 41163-228-50

Drug Facts

Active ingredients (in each geltab)
Acetaminophen 500 mg.....Pain reliever
Diphenhydramine HCl 25 mg.....Nighttime sleep-aid

Purposes

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 Kenvue Brands LLC, distributor of Extra Strength Tylenol[®] PM.

GLUTEN FREE

DISTRIBUTED BY UNFI, PROVIDENCE, RI 02903 USA

100% Quality GUARANTEED Like it or let us make it right. That's our quality promise. 855-423-2630

EQUALINE Extra Strength Pain Reliever Nighttime Sleep Aid

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	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: O8232NY3S)		
	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: 059QF0K00R)
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

#	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)