

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

1095-ELN-2022-0915

Drug Facts

<i>Active ingredients (in each caplet)</i>	<i>Purpose</i>
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

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.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

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 (1-800-222-1222). 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	<ul style="list-style-type: none"> ▪ take 2 caplets at bedtime ▪ do not take more than 2 caplets of this product in 24 hours
children under 12 years	<ul style="list-style-type: none"> ▪ do not use

Other information

- store between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information

Inactive ingredients

colloidal silicon dioxide, copovidone, croscarmellose sodium, FD&C blue #1, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

1-855-423-2630

PRINCIPAL DISPLAY PANEL

Equaline®

NDC 41163-515-01

compare to Extra Strength Tylenol® PM active ingredients*

extra strength

acetaminophen PM caplets

acetaminophen 500mg, diphenhydramine HCl 25mg

pain reliever/nighttime sleep aid

for adults

24 caplets

actual size

INK AND COATING FREE
FOR LOT AND
EXPIRATION STAMPING



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



Drug Facts

Active ingredients (in each caplet) **Purpose**
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 ■ hives ■ 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

Drug Facts (continued)

■ 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 ■ glaucoma
 ■ a breathing problem such as emphysema or chronic bronchitis
 ■ trouble urinating due to an enlarged prostate gland
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
 ■ 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.
 ■ pain gets worse or lasts more than 10 days
 ■ fever gets worse or lasts more than 3 days
 ■ redness or swelling is present
 ■ new symptoms occur

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 (1-800-222-1222). 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 caplets at bedtime
 ■ do not take more than 2 caplets of this product in 24 hours over
 children under 12 years
 ■ do not use

Other information

■ store between 20-25°C (68-77°F) in a dry place
 ■ retain carton for complete product information
Inactive ingredients colloidal silicon dioxide, copovidone, croscarmellose sodium, FD&C blue #1, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

1-855-423-2630
 DISTRIBUTED BY UNFI
 PROVIDENCE, RI 02908 USA
 *This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Extra Strength Tylenol® PM Caplets.

EQUALINE®
 extra strength
 acetaminophen 500 mg
 diphenhydramine HCl 25 mg
 pain reliever/nighttime sleep aid
 for adults
 100% Quality
 GUARANTEED
 Like it or let us make it right.
 That's our quality promise.
 855-423-2630

EQUALINE®

NDC 41163-515-01

compare to
 Extra Strength
 Tylenol® PM
 active ingredients*

extra strength
acetaminophen PM caplets
 acetaminophen 500 mg, diphenhydramine HCl 25 mg
 pain reliever/nighttime sleep aid
 for adults

24 caplets



actual size

NC

NC

NC

ACETAMINOPHEN PM EXTRA STRENGTH acetaminophen and diphenhydramine hydrochloride tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-515
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	AAA;1031
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-515-01	1 in 1 CARTON	09/01/2014	
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:41163-515-02	1 in 1 CARTON	09/01/2014	07/31/2020
2		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:41163-515-03	1 in 1 CARTON	09/01/2014	
3		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:41163-515-14	200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/2014	11/30/2018

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	09/01/2014	

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

Revised: 10/2024

United Natural Foods, Inc. dba UNFI