# ACETAMINOPHEN AND DIPHENHYDRAMINE HYDROCHLORIDE- acetaminophen and diphenhydramine hydrochloride tablet Aurohealth LLC

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#### **Drug Facts**

### Active ingredients (in each gelcap)

Acetaminophen USP 500 mg Diphenhydramine hydrochloride USP 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

- with other drugs containing acetaminophen
- more than 4,000 mg of acetaminophen in 24 hours
- 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
- if you are allergic to acetaminophen or any of the inactive ingredients in this product
- 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
- difficulty in urination due to enlargement of the 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 beverages
- do not drive a motor vehicle or operate machinery

#### Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- 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
- 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.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt 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
- adults and children 12 years and over
  - take 2 gelcaps at bedtime
  - do not take more than 2 gelcaps of this product in 24 hours.
- children under 12 years: do not use

#### Other information

avoid high humidity

- store at 20° to 25°C (68° to 77°F)
- use by expiration date on package

# Inactive ingredients

ammonium hydroxide, black iron oxide, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1, FD&C red #3, gelatin, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch (maize), propylene glycol, shellac glaze, talc, and titanium dioxide.

#### **Ouestions or comments?**

1-855-274-4122

Distributed by: AUROHEALTH LLC

279 Princeton- Hightstown Road, East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/16/2014

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 500 mg/25 mg (20 Gelcaps Bottle)

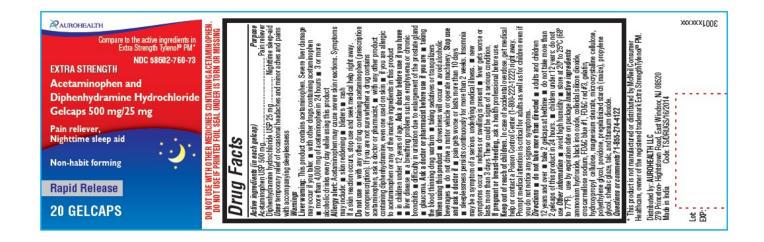
AUROHEALTH NDC 58602-760-73

EXTRA STRENGTH
Acetaminophen and
Diphenhydramine Hydrochloride
Gelcaps 500 mg/25 mg
Pain Reliever,
Nighttime Sleep Aid

Non-Habit Forming

**Rapid Release** 

**20 GELCAPS** 

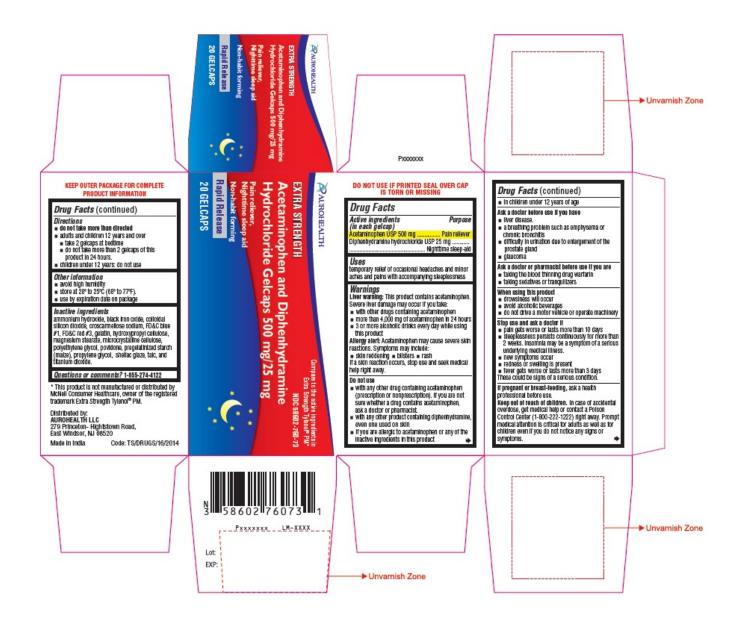


# PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 500 mg/25 mg (20 Gelcaps Bottle Carton)

AUROHEALTH
Compare to the active ingredients in Extra Strength Tylenol ®PM
NDC 58602-760-73

#### **EXTRA STRENGTH**

Acetaminophen and Diphenhydramine Hydrochloride Gelcaps 500 mg/25 mg Pain Reliever, Nighttime sleep aid Non-habit forming Rapid Release 20 GELCAPS



#### ACETAMINOPHEN AND DIPHENHYDRAMINE HYDROCHLORIDE

acetaminophen and diphenhydramine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-760
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg	
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg	

Inactive Ingredients	
Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B710)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	blue (Dark blue and Light blue with white band)	Score	no score
Shape	CAPSULE (Biconvex)	Size	20mm
Flavor		Imprint Code	T;6
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:58602-760- 14	1 in 1 CARTON	01/05/2021		
1		50 in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:58602-760- 73	1 in 1 CARTON	01/05/2021		
2		20 in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	01/05/2021	

Establishment				
Name	Address	ID/FEI	Business Operations	
APL HEALTHCARE LIMITED		650844777	analysis(58602-760), manufacture(58602-760)	

Revised: 11/2023 Aurohealth LLC