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

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 20º to 25°C (68º 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.

Questions 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: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE HYDROCHLORIDE (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: 46N107B71O)	
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			

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	

Labeler - Aurohealth LLC (078728447)

Establishment

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

Revised: 11/2023

Aurohealth LLC