ACETAMINOPHEN DIPHENHYDRAMINE HCL- acetaminophen diphenhydramine hcl tablet
WALGREEN CO.

Combo Pack

Pain reliever Acetaminophen USP, 500mg
Pain releiver/fever reducer
Extra strength

Pain reliever PM
Acetaminophen USP, 500mg/Diphenhydramine HCL USP, 25mg
Pain reliever/ Nighttime sleep-aid
Nighttime
Extra strength

Acetaminophen Gelcaps Active Ingredient (in each Gelcap)

Acetaminophen USP, 500 mg

Purpose

Pain reliever/fever reducer

Uses

■ temporarily relieves minor aches and pains due to:

■ headache

■ muscular aches

■ backache

■ minor pain of arthritis

■ the common cold

■ toothache

■ premenstrual and menstrual cramps

■ temporarily reduces fever

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

■ 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

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

Stop use and ask doctor if

■ pain gets worse or lasts more than 10 days

■ fever gets worse or lasts more than 3 days

■ new symptoms occur

■ redness or swelling is present

These could be signs of a serious condition.

If pregnant or breast-feeding

ask a health professional before use.

Keep out of the reach of children.

Keep out of the reach of children.

Overdose Warning

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 (see overdose warning)**

adults and children 12 years and over

■ take 2 gelcaps every 6 hours while symptoms last

■ do not take more than 6 gelcaps in 24 hours, unless directed by a doctor

■ do not take more than 10 days unless directed by a doctor

children under 12 years

■ ask a doctor

Other information

■ store at 20°-25°C (68°-77°F). See USP Controlled Room Temperature

■ avoid high humidity

■ see end panel for lot number and expiration date

Inactive ingredients

ammonium hydroxide, black iron oxide, colloidal silicon dioxide, croscarmellose sodium, D&C red#33, FD&C blue#1, FD&C red#40, FD&C yellow#6, gelatin, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, hypromellose, iron oxide red, isopropyl alcohol, n-butyl alcohol, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, stearic acid, titanium dioxide, yellow iron oxide.

Questions or comments?

call **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST.

Acetaminophen PM Gelcaps Active ingredient (in each gelcap)

Acetaminophen USP, 500 mg

Diphenhydramine HCl USP, 25 mg

Purposes

Pain reliever

Nighttime sleep aid

Uses

temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

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 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 the reach of children.

Keep out of the reach of children.

Overdose warning

Taking more than the recommended dose (overdose) may cause liver damage. 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 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

■ store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature.

■ see end panel for lot number and expiration date

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, D7C red#28, D&C yellow#10, FD7C blue#1, FD&C blue #2, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, isopropyl alcohol, microcrystalline cellulose, n-butyl alcohol, povidone, pregelatinized starch, propylene glycol, shellac glaze, stearic acid, titanium dioxide, triacetin.

Questions or comments?

call **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST.

Principal Display Panel

ACETAMINOPHEN DIPHENHYDRAMINE HCL

acetaminophen diphenhydramine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-9799

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
TRIACETIN (UNII: XHX3C3X673)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
GELATIN (UNII: 2G86QN327L)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
SHELLAC (UNII: 46N107B71O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
AMMONIA (UNII: 5138Q19F1X)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POVIDONE (UNII: FZ989GH94E)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	gray (Encapsulated gray color tablets with one red opaque and one blue-gray opaque hard gelatin shells) , gray (Encapsulated gray color tablets with dark blue opaque and light blue opaque hard gelatin shells)	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	G1;G3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9799-75	75 in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	03/03/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	03/03/2023	

Labeler - WALGREEN CO. (008965063)

Revised: 1/2024 WALGREEN CO.