

ALLERGY PLUS SINUS HEADACHE- acetaminophen 325 mg, diphenhydramine hcl 12.5 mg, phenylephrine hcl 5 mg tablet, film coated
Shield Pharmaceuticals Corp

Allergy plus Sinus Headache

Drug Facts

Active ingredient (in each liquid-filled capsule)

Acetaminophen 325 mg

Diphenhydramine HCl 12.5 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever

Antihistamine

Nasal decongestant

Uses

- temporarily relieves these symptoms of hay fever and the common cold:
- runny nose
- sneezing
- headache
- minor aches and pains
- nasal congestion
- temporarily relieves these additional symptoms of hay fever:
- itching of the nose or throat
- itchy, watery eyes

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
- hives
- facial swelling
- asthma (wheezing)
- shock

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 now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have

- liver disease
- glaucoma
- thyroid disease
- heart disease
- diabetes
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland
- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- do not exceed recommended dosage
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery
- avoid alcoholic beverages

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion gets worse or lasts more than 7 days

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

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.1(800)222-1222

Directions

- do not use more than directed
- adults and children 12 years and over: take 2 caplets every 4 hours
- do not take more than 10 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- store at 25°C (77°F); excursions permitted between 15°C-30°C (59°F-86°F)

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, magnesium stearate*, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, polyvinyl pyrrolidone, povidone*, pregelatinized starch, stearic acid powder, talc, titanium dioxide *may contain these ingredients

Questions or comments?

1-800-373-6981 (toll-free)

Distributed by:

Shield Pharmaceuticals Corp.

Ronkonkoma, NY 11779

PRINCIPAL DISPLAY PANEL

Allergy plus Sinus headache

Acetaminophen

Diphenhydramine HCl

Phenylephrine HCl

Pain reliever / Antihistamine / Nasal decongestant

Relieves:

- runny nose • sneezing • headache
- minor aches and pains • hay fever
- nasal congestion • itching of the nose or throat
- itchy, watery eyes

Carton



ALLERGY PLUS SINUS HEADACHE

acetaminophen 325 mg, diphenhydramine hcl 12.5 mg, phenylephrine hcl 5 mg tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83059-0106
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	325 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: T032614510)		DIPHENHYDRAMINE	

DIPHENHYDRAMINE HYDROCHLORIDE (UNII: 1CZD6JAD4U) (DIPHENHYDRAMINE - UNII:8GTS82S83M)		DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE	5 mg	
Inactive Ingredients				
Ingredient Name			Strength	
STARCH, CORN (UNII: O8232NY3SJ)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
POVIDONE (UNII: FZ989GH94E)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	green	Score	no score	
Shape	OVAL	Size	19mm	
Flavor		Imprint Code	44;464;SD36	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83059-0106-1	1 in 1 CARTON	11/07/2025	
1		12 in 1 BLISTER PACK; 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	11/07/2025	

Labeler - Shield Pharmaceuticals Corp (118724924)