

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

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**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°-30°C (59°-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***

croscarmellose sodium, colloidal silicon dioxide, dibasic calcium phosphate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, starch, talc, titanium dioxide

### ***Questions or comments?***

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

**Shield Pharmaceuticals Corp.**

Hauppauge, NY 11788

### **PRINCIPAL DISPLAY PANEL**

Allergy plus  
Sinus headache  
Acetaminophen

Diphenhydramine HCl  
Phenylephrine HCl  
Pain reliever / Antihistamine /

Relieves:

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

Labe

**ValuRx** Multi-symptom

**Allergy plus Sinus headache**

Acetaminophen  
Diphenhydramine HCl  
Phenylephrine

Pain reliever / Antihistamine / Nasal decongestant

**12 caplets**

**DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

**Active ingredient (in each caplet)**

|                                  |                    |
|----------------------------------|--------------------|
| Acetaminophen 325 mg.....        | Pain reliever      |
| Diphenhydramine HCl 12.5 mg..... | Antihistamine      |
| Phenylephrine HCl 5 mg.....      | 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 before use.

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock

If a skin reaction occurs, stop use and seek medical help right away. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

**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°-30°C (59°-86°F)

**Questions or comments? 1-800-373-6981 (toll-free)**

See carton for complete Warnings and list of Inactive Ingredients

406170

Distributed by:  
**Shield Pharmaceuticals Corp.**  
Hauppauge, NY 11788

Made in India  
ORG. 08/24  
LOT: SL D24041  
EXP: 05/2026

Carton



## ALLERGY PLUS SINUS HEADACHE

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

### Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:83059-0044 |
| <b>Route of Administration</b> | ORAL           |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength             | Strength |
|---|-------------------------------|----------|
| <b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)                   | ACETAMINOPHEN                 | 325 mg   |
| <b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 12.5 mg  |
| <b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)     | PHENYLEPHRINE                 | 5 mg     |

## Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>STARCH, CORN</b> (UNII: O8232NY3SJ)                        |          |
| <b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)                |          |
| <b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP) |          |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)                  |          |
| <b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)          |          |
| <b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)    |          |
| <b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)      |          |
| <b>POVIDONE</b> (UNII: FZ989GH94E)                            |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                     |          |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)                        |          |
| <b>TALC</b> (UNII: 7SEV7J4R1U)                                |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                    |          |

## Product Characteristics

|                 |       |                     |          |
|-----------------|-------|---------------------|----------|
| <b>Color</b>    | green | <b>Score</b>        | no score |
| <b>Shape</b>    | OVAL  | <b>Size</b>         | 19mm     |
| <b>Flavor</b>   |       | <b>Imprint Code</b> | SD18     |
| <b>Contains</b> |       |                     |          |

## Packaging

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:83059-0044-1 | 1 in 1 PACKAGE                                    | 09/02/2024           |                    |
| 1 |                  | 15 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 | M012                                     | 09/02/2024           |                    |

**Labeler** - Shield Pharmaceuticals Corp (118724924)

Revised: 10/2025

Shield Pharmaceuticals Corp