

**ALLERGY PLUS SINUS HEADACHE- acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, coated**  
**Spirit Pharmaceuticals LLC**

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**Allergy plus Sinus Headache**

**Drug Facts**

***Active ingredients (in each caplet)***

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
- 3 or more alcoholic drinks every day while using this product
- with other drugs containing acetaminophen

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

- blisters
- rash
- skin reddening

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

### **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 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 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 25oC (77oF); excursions permitted between 15o-30oC (59o-86oF)

### ***Inactive Ingredients***

microcrystalline cellulose, pregelatinized starch, croscarmellose sodium, polyvinyl pyrrolidone, colloidal silicon dioxide, stearic acid powder, polyvinyl alcohol, polyethylene glycol, titanium dioxide, talc, tartrazine yellow lake, brilliant blue lake, indigo carmine lake

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

1-888-333-9792

**READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION**

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

Distributed By:  
Spirit Pharmaceuticals, LLC  
Ronkonkoma, NY 11779

ORIG 05/21

Made in India

**label and carton**

**label**

VALUHEALTH

Multi-symptom  
allergy plus sinus  
headache

Acetaminophen - Pain Reliever,  
Diphenhydramine HCl - Antihistamine  
Phenylephrine HCl 5 mg -  
Nasal decongestant

12 caplets

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

KEEP OUTER CARTON FOR COMPLETE  
WARNINGS AND PRODUCT INFORMATION

**Active ingredients (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  
■ 3 or more alcoholic drinks every day while using this product  
■ with other drugs containing acetaminophen  
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) night or day. 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 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?** 1-888-333-4792

Distributed By: Spint Pharmaceuticals, LLC

Romulus, NY 11779

Made in India 88924-6

LOT:

EXP:

carton



# ALLERGY PLUS SINUS HEADACHE

acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-4190
<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>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>STARCH, POTATO</b> (UNII: 8I089SAH3T)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>PYRROLIDINE</b> (UNII: LJU5627FYV)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	

## Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	S504
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4190-1	1 in 1 CARTON	11/11/2021	
1		12 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	11/11/2021	

Revised: 12/2023

Spirit Pharmaceuticals LLC