

# SEVERE ALLERGY PLUS SINUS HEADACHE- acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride tablet, coated

## TopCare

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**TCR - 1126 - 2019-1007**

### **Drug Facts**

<b>Active ingredients (in each caplet)</b>	<b>Purpose</b>
Acetaminophen 325 mg	Pain reliever
Diphenhydramine HCl 25 mg	Antihistamine
Phenylephrine HCl 5 mg	Nasal decongestant

### **Uses**

- temporarily relieves these symptoms of hay fever or other upper respiratory allergies:
  - runny nose
  - sneezing
  - headache
  - minor aches and pains
  - nasal congestion
  - sinus congestion and pressure
  - itchy, watery eyes
  - itching of the nose or throat

### **Warnings**

#### **Liver warning**

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 12 caplets in 24 hours, which is the maximum daily amount
- 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
- 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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to an enlarged 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
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- redness or swelling is present
- pain or nasal congestion gets worse or lasts more than 7 days
- new symptoms occur
- 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.**

**Overdose warning**

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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	<ul style="list-style-type: none"><li>▪ take 2 caplets every 4 hours</li><li>▪ do not to take more than 12 caplets in 24 hours</li></ul>
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children under 12  
years

- ask a doctor

### Other information

- store between 20°-25°C (68°-77°F) in a dry place
- retain carton for complete product information

### Inactive ingredients

colloidal silicon dioxide, copovidone, croscarmellose sodium, FD&C blue #1, hypromellose, lactose anhydrous, magnesium stearate, povidone, pregelatinized starch, propylene glycol, sodium starch glycolate, stearic acid, titanium dioxide, triacetin

### PRINCIPAL DISPLAY PANEL

NDC 36800-500-02

TopCare health

MAXIMUM STRENGTH

Severe Allergy Plus Sinus Headache

ACETAMINOPHEN - PAIN RELIEVER

DIPHENHYDRAMINE HCL - ANTIHISTAMINE

PHENYLEPHRINE HCL - NASAL DECONGESTANT

RELIEF OF:

Sinus Headache

Sneezing

Itchy, Watery Eyes

Runny Nose

Itchy Throat

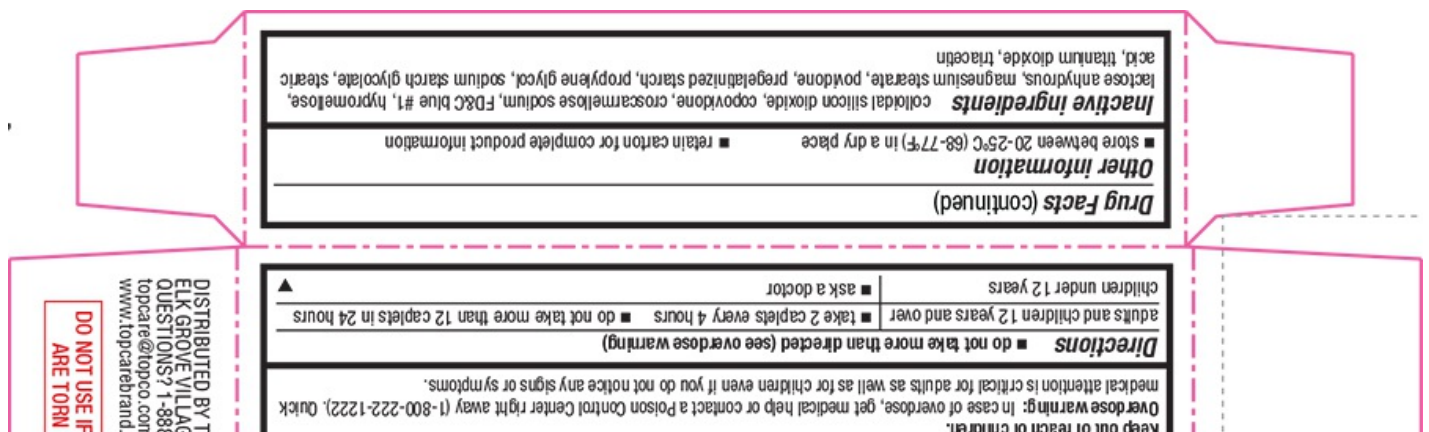
Sinus Congestion

Sinus Pressure

OUR PHARMACISTS RECOMMEND

20 CAPLETS

actual size





F112602TCR\_R1

**Warnings**  
 This product contains acetaminophen. Severe liver damage may occur if you take more than 12 caplets in 24 hours, which is the maximum daily amount.  
 ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product  
 ■ 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 ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ glaucoma ■ trouble urinating due to an enlarged 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  
 ■ avoid alcoholic drinks  
**Stop use and ask a doctor if** ■ nervousness, dizziness, or sleepiness occur ■ redness or swelling is present ■ fever gets worse or lasts more than 7 days  
 ■ new symptoms occur  
 ■ 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.

**Drug Facts (continued)**

**Active ingredients (in each caplet)**  
 Acetaminophen 325 mg.....Pain reliever  
 Diphenhydramine HCl 25 mg.....Antihistamine  
 Phenylephrine HCl 5 mg.....Nasal decongestant

**Purpose**  
 Pain relief

**Uses** ■ temporarily relieves these symptoms of hay fever or other upper respiratory allergies:  
 ■ sneezing  
 ■ runny nose  
 ■ headache  
 ■ nasal congestion  
 ■ itchy, watery eyes  
 ■ sinus congestion and pressure  
 ■ minor aches and pains

**Drug Facts (continued)**  
 ■ skin reddening ■ blisters ■ rash

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 1-423-0139  
 .com



This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

BUSTER UNITS OR BROKEN



MAXIMUM STRENGTH

# Severe Allergy Plus Sinus Headache

SEVERE

- ACETAMINOPHEN - PAIN RELIEVER
- DIPHENHYDRAMINE HCl - ANTIHISTAMINE
- PHENYLEPHRINE HCl - NASAL DECONGESTANT



**RELIEF OF:** • Sinus Headache • Sneezing  
 • Itchy, Watery Eyes • Runny Nose • Itchy Throat  
 • Sinus Congestion • Sinus Pressure

20 CAPLETS



actual size

NC

NC

NC

NDC-36800-500-02

# SEVERE ALLERGY PLUS SINUS HEADACHE

acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride tablet, coated

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-500
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: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

## Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	AAA;116
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-500-02	2 in 1 CARTON	07/01/2013	
1		10 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 final	part341	07/01/2013	

**Labeler** - TopCare (006935977)

Revised: 10/2019

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