

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.

TCR - 1125 - 2019-1007

Drug Facts

Active ingredients (in each caplet)	Purpose
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 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
- pain or nasal congestion gets worse or lasts more than 7 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 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 use more than directed (see overdose warning)

adults and children 12 years and over	<ul style="list-style-type: none">▪ take 2 caplets every 4 hours▪ do not take more than 12 caplets in 24 hours
children under 12	<ul style="list-style-type: none">▪ ask a doctor

years

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, color black, copovidone, croscarmellose sodium, D&C yellow #10, 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 36800-501-02

TopCare health

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

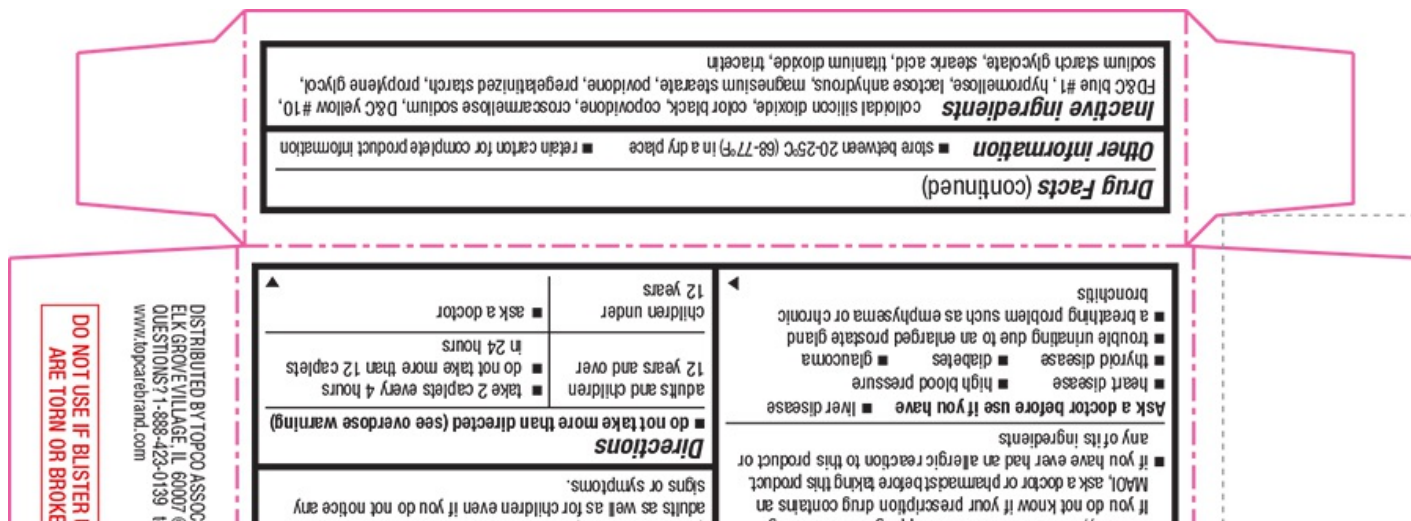
Sinus Congestion

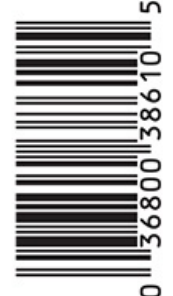
Sinus Pressure

OUR PHARMACISTS RECOMMEND

24 CAPLETS

actual size





F112502TCR_R1

Drug Facts (continued)

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.

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
- Inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug.

Drug Facts (continued)

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
- pain or nasal congestion gets worse or lasts more than 7 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 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

Drug Facts

Active ingredients (in each caplet)

- Acetaminophen 325 mg.....Pain reliever
- Diphenhydramine HCl 12.5 mg.....Antihistamine
- Phenylephrine HCl 5 mg.....Nasal decongestant

Purpose

Temporarily relieves these symptoms of hay fever and the common cold:

- 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

Drug Facts (continued)

Uses

- temporarily relieves these symptoms of hay fever and the common cold:
- runny nose ■ sneezing ■ headache
- minor aches and pains ■ nasal congestion
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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



24 CAPLETS



actual size



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

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 topcare@topco.com

INITS

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ALLERGY PLUS SINUS HEADACHE

acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-501
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	12.5 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)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
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	green	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	AAA;115
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-501-02	2 in 1 CARTON	07/01/2013	
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 final	part341	07/01/2013	

Labeler - TopCare (006935977)

Revised: 10/2019

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