

ACETAMINOPHEN, DIPHENHYDRAMINE HYDROCHLORIDE, PHENYLEPHRINE HYDROCHLORIDE- acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride tablet, coated
AAA Pharmaceutical, Inc.

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.

Acetaminophen, Diphenhydramine HCl, Phenylephrine HCl Tablets -1125

Drug Facts

<i>Active ingredients (in each caplet)</i>	<i>Purpose</i>
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

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.

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

Taking more than the recommended dose (overdose) may cause liver damage. 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 years	<ul style="list-style-type: none"> • do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

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, methylparaben, povidone, pregelatinized starch, propylene glycol, propylparaben, sodium starch glycolate, stearic acid, titanium dioxide, triacetin

Distributed by:

AAA Pharmaceutical, Inc.
681 Main Street
Lumberton, NJ 08048

PRINCIPAL DISPLAY PANEL - 24 Caplet Blister Pack Carton***RESTORE u***

NDC 57344-125-02

† COMPARE TO THE ACTIVE
INGREDIENTS IN BENADRYL[®]
ALLERGY PLUS SINUS HEADACHE

***Allergy &
Sinus Headache***

Pain Reliever, Antihistamine, Nasal Decongestant
Acetaminophen, Diphenhydramine HCl, Phenylephrine HCl

Relieves:

- Sneezing
- Itchy, Watery Eyes
- Runny Nose
- Sinus Congestion
- Sinus Pain & Pressure
- Sinus Headache

24 CAPLETS

NC

<p>When using this product</p> <ul style="list-style-type: none"> do not exceed recommended dosage taking sedatives or tranquilizers taking the blood thinning drug warfarin <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> a breathing problem such as emphysema or chronic bronchitis trouble urinating due to an enlarged prostate gland thyroid disease diabetes glaucoma heart disease high blood pressure liver disease <p>Ask a doctor before use if you have</p> <p>MAOI, ask a doctor or pharmacist before taking this product. If you do not know if your prescription drug contains an MAOI drug, or if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or 2 weeks after stopping the MAOI drug.</p> <p>Do not use</p> <ul style="list-style-type: none"> 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, or other drugs containing acetaminophen 3 or more alcoholic drinks every day while using this product more than 12 caplets in 24 hours, which is the severe liver damage may occur if you take <p>Liver warning: This product contains acetaminophen.</p> <p>Warnings (continued)</p>	
<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> do not use more than directed (see overdose warning) adults and children <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 years <ul style="list-style-type: none"> do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage 	
<p>Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. 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.</p> <p>Keep out of reach of children.</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> 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 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. <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Drug Facts (continued)</p>	

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<p>Drug Facts</p> <p>Active ingredients (in each caplet)</p> <p>Acetaminophen 325 mg.....Pain reliever</p> <p>Diphenhydramine HCl 12.5 mg.....Antihistamine</p> <p>Phenylephrine HCl 5 mg.....Nasal decongestant</p>	<p>Purpose</p> <p>the common cold;</p> <p>temporarily relieves these symptoms of hay fever and</p> <p>the common cold:</p> <ul style="list-style-type: none"> runny nose sneezing headache minor aches and pains nasal congestion itching of the nose or throat itchy, watery eyes <p>temporarily relieves these additional symptoms of hay fever:</p> <ul style="list-style-type: none"> nasal congestion nasal congestion
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<p>Drug Facts (continued)</p>	



NDC 57344-125-02
COMPARE TO THE ACTIVE INGREDIENTS IN BENADRYL® ALLERGY PLUS SINUS HEADACHE

Allergy & Sinus Headache

Pain Reliever, Antihistamine, Nasal Decongestant
Acetaminophen, Diphenhydramine HCl, Phenylephrine HCl

- Relieves:
- Sneezing
 - Itchy, Watery Eyes
 - Runny Nose
 - Sinus Congestion
 - Sinus Pain & Pressure
 - Sinus Headache



F112502RES_R0

Distributed by:
AAA Pharmaceutical, Inc.
681 Main Street
Lumberton, NJ 08048

is not manufactured or
distributed by Benadryl®
sinus Headache

IF BLISTER UNITS
IN OR BROKEN

24 CAPLETS

† This product distributed by Healthcare, d Allergy Plus S

DO NOT USE ARE TOP

Drug Facts (continued)
Other information ■ store between 20°-25°C (68°-77°F) in a dry place ■ retain carton for complete product information
Inactive ingredients colbital silicon dioxide, color black, copovidone, croscarmellose sodium, D&C yellow #10, F&C blue #1, hypromellose, lactose anhydrous, magnesium stearate, methylparaben, povidone, pregelatinized starch, propylene glycol, propylparaben, sodium starch glycolate, stearic acid, titanium dioxide, triacetin

ACETAMINOPHEN, DIPHENHYDRAMINE HYDROCHLORIDE, PHENYLEPHRINE HYDROCHLORIDE

acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57344-125
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: H3R47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
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:57344-125-02	2 in 1 CARTON	12/22/20 12	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:57344-125-03	4 in 1 CARTON	12/22/20 12	
2		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	12/22/20 12	

Labeler - AAA Pharmaceutical, Inc. (181192162)

Establishment

Name	Address	ID/FEI	Business Operations
AAA Pharmaceutical, Inc.		080164679	manufacture(57344-125)

Establishment

Name	Address	ID/FEI	Business Operations
AAA Pharmaceutical, Inc.		181192162	pack(57344-125)

Revised: 12/2018

AAA Pharmaceutical, Inc.