ALLERGY PLUS SINUS HEADACHE- acetaminophen, diphenhydramine hcl and phenylephrine hcl tablet, film coated
GREENBRIER INTERNATIONAL, 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.

Assured 44-464

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
- diabetes
- heart disease
- thyroid disease
- 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

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, croscarmellose sodium, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

ASSURED™

MULTI-SYMPTOM
ALLERGY
PLUS SINUS HEADACHE

• **Acetaminophen -** *Pain Reliever*
• **Diphenhydramine HCl** - *Antihistamine*
• **Phenylephrine HCl** - *Nasal Decongestant*

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

Actual Size

12 caplets

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

50844 REV0517E46402

ITEM# 163821
Distributed by: **Greenbrier International, Inc.**
Chesapeake, VA 23320 USA

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
- diabetes
- heart disease
- thyroid disease
- 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

- fever gets worse or lasts more than 3 days
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Questions or comments? 1-800-426-9391

50844 REV0517E46402

ITEM# 163821
Distributed by: **Greenbrier International, Inc.**
Chesapeake, VA 23320 USA

B-0316-464-02-R
REV0517E46402

12 caplets

Actual Size

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

- **Acetaminophen** - Pain Reliever
- Diphenhydramine HCl - Antihistamine
- Phenylephrine HCl - Nasal Decongestant

ALLERGY
PLUS SINUS HEADACHE

MULTI-SYMPTOM

ASSURED

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

OMIT B1

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MULTI-SYMPTOM
ALLERGY
PLUS SINUS HEADACHE
ASSURED
12 caplets

Drug Facts
KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Active ingredients (in each caplet)	Purpose
Acetaminophen 325 mg	Pain reliever
Diphenhydramine HCl 12.5 mg	Antihistamine
Phenylephrine HCl 5 mg	Nasal decongestant

Drug Facts (continued)

Uses
- temporarily relieves these symptoms of hay fever and the common cold:
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  - minor aches and pains
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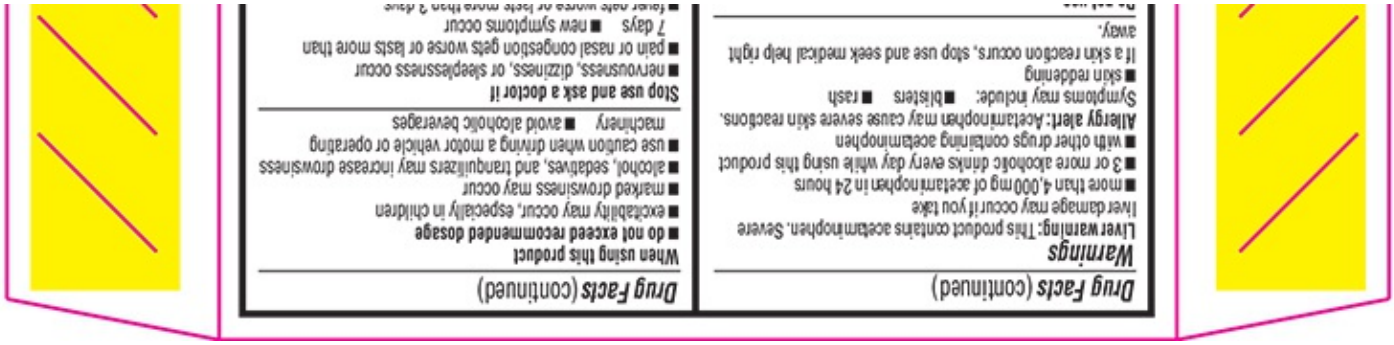

Assured 44-464

ALLERGY PLUS SINUS HEADACHE

acetaminophen, diphenhydramine hcl and phenylephrine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:33992-0464
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**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	GREEN	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	44;464
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-0464-2	1 in 1 CARTON	06/15/2005	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:33992-0464-8	2 in 1 CARTON	06/15/2005	
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	06/15/2005	

Labeler - GREENBRIER INTERNATIONAL, INC. (610322518)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(33992-0464)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(33992-0464)

Revised: 9/2020 GREENBRIER INTERNATIONAL, INC.