

DAYTIME SINUS RELIEF- acetaminophen and phenylephrine hydrochloride capsule, liquid filled

ASSURED / DOLLAR TREE (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.

DRUG FACTS

Active ingredients (in each softgel)

Acetaminophen 325 mg

Phenylephrine HCl 5 mg

Purposes

Pain reliever

Nasal decongestant

Uses

temporarily relieves sinus symptoms:

- sinus pain
- headache
- nasal and sinus congestion

Warnings

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

- more than 4 doses in 24 hours, which is the maximum daily amount for this product
- with any 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.
- 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
- thyroid disease
- diabetes
- high blood pressure
- difficulty in urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

**When using this product,
do not exceed recommended dosage**

Stop use and ask a doctor if

- redness or swelling is present
- you get nervous, dizzy, or sleepless
- fever gets worse or lasts more than 3 days
- new symptoms occur
- symptoms do not get better within 7 days or are accompanied by a fever

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health care professional before use.

Keep out of reach of children.

Overdose warning: Taking more than the recommended dose could cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Directions

- do not use more than directed (see **Overdose warning**)
- do not exceed 4 doses in 24 hours
- **when using other Daytime or Nighttime products, carefully read each label to insure correct dosing**

adults and children 12 years of age and over	take 2 softgels with water every 4 hours
children 4 to under 12 years of age	ask a doctor
children under 4 years of age	do not use

Other information

- store at room temperature 15° - 30° C (59°- 86° F) and avoid excessive heat

Inactive ingredients

FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special, edible white ink.

Questions or comments?

call 1-877-753-3935 Monday- Friday 9AM- 5PM EST

Principal Display Panel

Compare to active ingredients in Vicks® Dayquil® Sinex® LiquiCaps® *

***This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® Dayquil® Sinex® LiquiCaps®**

DAYTIME

Sinus Relief

Liquid Capsules

Non- drowsy

Acetaminophen- Sinus Headache and Pain

Phenylephrine HCl- Sinus Pressure and Congestion

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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

Distributed by:

Greenbrier International, INC.

500 Volvo parkway, Chesapeake, VA 23320

PRODUCT OF CANADA

****Product may vary from image shown**

Product Label

0 3 1 3 3 2 9 1



V60X4

<p>Drug Facts</p> <p>Active ingredients (in each softgel)</p> <p>Acetaminophen 325 mg Pain reliever</p> <p>Phenylephrine HCl 5 mg Nasal decongestant</p> <p>Uses</p> <p>temporarily relieves sinus symptoms: sinus pain, headache, nasal and sinus congestion</p> <p>Warnings</p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take: more than 4 doses in 24 hours, which is the maximum daily amount for this product with any other drugs containing acetaminophen 3 or more alcoholic drinks every day while using this product</p> <p>Do not use</p> <p>with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. 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.</p> <p>Ask a doctor before use if you have liver disease, heart disease, thyroid disease, diabetes, high blood pressure, difficulty in urinating due to an enlarged prostate gland</p> <p>Ask a doctor or pharmacist before use if you are taking the blood-thinning drug warfarin.</p> <p>When using this product, do not exceed recommended dosage.</p> <p>Stop use and ask a doctor if</p>	<p>Drug Facts (continued)</p> <p>redness or swelling is present you get nervous, dizzy, or sleepless fever gets worse or lasts more than 3 days new symptoms occur symptoms do not get better within 7 days or are accompanied by a fever These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health care professional before use. Keep out of reach of children.</p> <p>Overdose warning: Taking more than the recommended dose could cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.</p> <p>Directions</p> <p>do not use more than directed (see Overdose warning) do not exceed 4 doses in 24 hours when using other Daytime and Nighttime products, carefully read each label to ensure correct dosing</p> <table border="1"> <tr> <td>adults and children 12 years of age and over</td> <td>take 2 softgels with water every 4 hours</td> </tr> <tr> <td>children 4 to under 12 years of age</td> <td>ask a doctor</td> </tr> <tr> <td>children under 4 years of age</td> <td>do not use</td> </tr> </table> <p>Other information</p> <p>Store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat</p> <p>Inactive ingredients FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special, white edible ink</p> <p>Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST</p>	adults and children 12 years of age and over	take 2 softgels with water every 4 hours	children 4 to under 12 years of age	ask a doctor	children under 4 years of age	do not use
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DAYTIME

Sinus Relief Liquid Capsules

8 softgels

DAYTIME

Sinus Relief Liquid Capsules



COMPARE TO ACTIVE INGREDIENTS IN
VICKS® DAYQUIL® SINEX® LIQUICAPS®

NDC 33992-1100-8

DAYTIME

Sinus Relief Liquid Capsules



Acetaminophen - Sinus Headache and Pain
Phenylephrine HCl - Sinus Pressure and Congestion

NON-DROWSY

8 softgels

Acetaminophen, Phenylephrine HCl

DISTRIBUTED BY
GREENBRIER INTERNATIONAL, INC.
500 VOLVO PARKWAY, CHESAPEAKE, VA 23320
Product of Canada
PLD-A
FC001742

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**Product may vary from image shown



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

Lot No.:
Exp. Date:

Daytime sinus relief liquid capsules

DAYTIME SINUS RELIEF

acetaminophen and phenylephrine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-1100
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONES (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	CAPSULE	Size	22mm
Flavor		Imprint Code	48A
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-1100-8	1 in 1 CARTON		
1		8 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	12/09/2013	

Labeler - ASSURED / DOLLAR TREE (Greenbrier International, Inc.) (610322518)

Revised: 11/2013

ASSURED / DOLLAR TREE (Greenbrier International, Inc.)