

**SOUND BODY COLD AND FLU RELIEF- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution**

**Big Lots Stores, 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.*

-----

**Big Lots, Inc Cold & Flu Relief Drug Facts**

**Active ingredients (in each 15 mL)**

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

**Purpose**

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

**Uses**

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion and pressure
- cough due to minor throat and bronchial irritation
- minor aches and pains
- headache
- fever
- sore throat
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

**Warnings**

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

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 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.

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

### **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.
- 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
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

### **Ask a doctor or pharmacist before use if you are**

taking the blood thinning drug warfarin

### **When using this product**

**do not use more than directed**

**Stop use and ask a doctor if**

- you get nervous, dizzy or sleepless
- pain, nasal congestion, or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts. 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**

- take only as directed – see Overdose warning
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 4 hrs
children 6 to under 12 yrs	15 mL every 4 hrs
children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

**Other information**

- **each 15 mL contains:** sodium 6 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

**Inactive ingredients**

butylated hydroxyanisole, edetate disodium, FD&C yellow #6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum

**Questions?**

**1-800-719-9260**

**Package/Label Principal Display Panel**

SOUNDBODY™

Compare to the Active Ingredients in Vicks® DayQuil® Severe Cold & Flu

Non-Drowsy

DAYTIME

Cold & Flu Relief Severe

Pain Reliever / Fever Reducer -

Acetaminophen

Cough Suppressant -

Dextromethorphan HBr

Expectorant - Guaifenesin

Nasal Decongestant -

Phenylephrine HCl

ALCOHOL FREE

MAX STRENGTH

12 FL OZ (355 mL)



Compare to the Active Ingredients in Vicks® DayQuil® Severe Cold & Flu\*

# Non-Drowsy DAYTIME Cold & Flu Relief Severe

Pain Reliever / Fever Reducer - Acetaminophen  
Cough Suppressant - Dextromethorphan HBr  
Expectorant - Guaifenesin  
Nasal Decongestant - Phenylephrine HCl

ALCOHOL FREE

MAX STRENGTH

12 FL OZ (355 mL)

: 60340 TM F5

Packaged by  
Perrigo Company for:  
Big Lots Stores, Inc.  
P.O. Box 28523, Columbus, OH 43228-0523  
V#5003185 ITEM#60340

## PARENTS:

Learn about teen medicine abuse

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

GLUTEN FREE

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

### Drug Facts

#### Active ingredients (in each 15 mL)

Active ingredients (in each 15 mL)	Purpose
Acetaminophen 325 mg.....	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg.....	Cough suppressant
Guaifenesin 200 mg.....	Expectorant
Phenylephrine HCl 5 mg.....	Nasal decongestant

**Uses** temporarily relieves common cold/flu symptoms: ■ sinus congestion and pressure ■ nasal congestion ■ minor aches and pains ■ headache ■ sore throat ■ fever ■ cough due to minor throat and bronchial irritation ■ reduces swelling of nasal passages ■ promotes nasal and/or sinus drainage ■ temporarily restores freer breathing through the nose ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

### Warnings

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if ■ adult takes more than 4,000 mg of acetaminophen in 24 hours ■ child takes more than 5 doses in 24 hours ■ taken with other drugs containing acetaminophen ■ adult has 3 or more alcoholic drinks every day while using this product

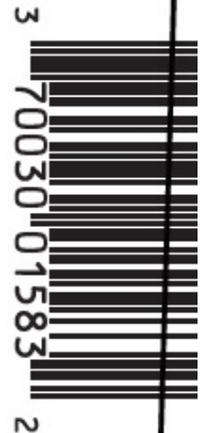
**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

PEEL BACK AT CORNER FOR MORE INFORMATION

: 60340 TM B1



**Drug Facts**  
(continued)

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

**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.  
■ 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
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

**Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin**

**Drug Facts**  
(continued)

**When using this product do not use more than directed**

**Stop use and ask a doctor if** ■ you get nervous, dizzy or sleepless ■ pain, nasal congestion, or cough gets worse or lasts more than 5 days (children) or 7 days (adults) ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ new symptoms occur ■ cough comes back or occurs with rash or headache that lasts. 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** ■ take only as directed – see Overdose warning ■ only use the dose cup provided ■ do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 4 hrs
children 6 to under 12 yrs	15 mL every 4 hrs
children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

**Other information** ■ each 15 mL contains: sodium 6 mg ■ store at 20-25°C (68-77°F). Do not refrigerate.

**Inactive ingredients**

butylated hydroxyanisole, edetate disodium, FD&C yellow #6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum

**Questions?**

1-800-719-9260

\*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® DayQuil® Severe Cold & Flu.

ADHESIVE AREA  
NO COATING • NO VARNISH • NO TYPE

ADHESIVE AREA  
NO COATING • NO VARNISH • NO TYPE

**SOUND BODY COLD AND FLU RELIEF**

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:50594-016

Route of Administration ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 15 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	
<b>SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM</b> (UNII: 3980JIH2SW)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	ORANGE (clear)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	FRUIT, MENTHOL	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50594-016-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/03/2016	

