SOUND BODY DAYTIME COLD AND FLU RELIEF NIGHTTIME COLD AND FLU RELIEF- acetaminophen, dextromethorphan hbr, doxylamine succinate, guaifenesin, phenylephrine hcl 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. DayTime Cold & Flu NightTime Cold & Flu Drug Facts

Nighttime Severe Cold & Flu Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Doxylamine succinate 12.5 mg

Phenylephrine HCl 10 mg

Purpose

Pain reliever/fever reducer Cough suppressant Antihistamine Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion and pressure
- minor aches and pains
- headache
- fever
- sore throat
- runny nose and sneezing
- cough due to minor throat and bronchial irritation
- cough to help you sleep
- reduces swelling of nasal passages
- promotes nasal and/or sinus drainage
- temporarily restores freer breathing through the nose

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
- 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.

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
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- · persistent or chronic cough as occurs with smoking, asthma, or emphysema
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- do not use more than directed
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, nasal congestion, or cough 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
- 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	30 mL every 4 hrs
yrs & over	
children 4 to under 12	ask a doctor
yrs	
children under 4 yrs	do not use

Other information

- each 30 mL contains: sodium 44 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

alcohol, anhydrous citric acid, D&C yellow #10, edetate disodium, FD&C green #3, FD&C

yellow #6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution, sucralose

Questions or comments?

1-800-719-9260

Daytime Severe Cold & Flu 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 or comments?

1-800-719-9260

Package/Label Principal Display Panel

COMBO PACK

SOUND BODY[™]

Compare to the Active Ingredients in Vicks $^{\rm \tiny R}$ DayQuil $^{\rm \tiny R}$ 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)

SOUND BODY[™]

Compare to the Active Ingredients in Vicks $^{\circledR}$ NyQuil $^{\circledR}$ Severe Cold & Flu

NIGHTTIME

Cold & Flu Relief Severe

Pain Reliever / Fever Reducer - Acetaminophen

Cough Suppressant - Dextromethorphan HBr

Antihistamine - Doxylamine Succinate

Nasal Decongestant - Phenylephrine HCl

10% ALCOHOL

MAX STRENGTH

12 FL OZ (355 mL)

COMBO PACK

DO NOT USE IF PRINTED INECKBAND IS BROKEN OR MISSING





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

Non-Drowsy

Cold & Flu Relief Severe

Pain Reliever / Fever Reducer-Ac etaminop hen Cough Suppressant -Dextromethorphan HBr Expectorant - Guaifenes in Nasal Decongestant -Phenylephrine HCI

ALCOHOL FREE

MAX STRENGTH

12 **FL** 0Z (355 mL)

NIGHTTIME

Cold & Flu Relief Severe

Pain Reliever / Fever Reducer -Acetaminophen Cough Suppressant -Dextromethorphan HBr Antihistamine -Doxylamine Succinate Nasal Decongestant -Phenylephrine HCI

10% ALCOHOL

MAX STRENGTH

12 FL OZ (355 mL)



www.StopMedicineAbuse.org

GLUTEN FREE

"These products are not manufactured or clinificated by Product & Gamille, clinificator of Victor® Day Guille Service Cald & Ru and Victor® NyQuil® Service Cold & Ru.

Packaged by Perrigo Company for: Big Lots Stones, Inc. R.O. Box 29523 Columbus, OH 43228-0523 V#5003185 ITB##86002





Hightihme Severe Cold & Flu Daytime Savers Cold & Fit Drug Facts Drug Facts Active ingredients (in each 30 mL) Active ingredients (in each 15 mL) Ригрове Cedron rhophan HB 10 mg. Cough suppressur Gastlerein 200mg. Expeditors Phenylephine HC/5 mg. Masal decongestan Cooylamine succisale 12.5 mg..... Phenyle phrine HCI 10 mg. Nasal desorgestant Uses bergoratly releves conven oxiditus/preploms: a small coapetion — shall coapetible and pressure a cough due to nison threat and trondhis intribion a nilmor aches and pates — sheatche — sheer — sore threat a reduces swelling of seed passages The coapetible of the coapetible of the coapetible coapetible of the coapetible coa temporarily reduces free breathing through the ruse promotes seal and/or sinus distrings approximate seal and/or sinus distrings ade jo looses the playing including and this broadhall secretions to ad the broadhall passageways of botherscore nursus and make coughs more productive Warmings User warring: This product contains acetaminophers. Severe liver damage may countf Warmings Uvor warning This product contains acetaminophen, Severe liver damage may occur if you take more than 4,000 mg of acetaminophes in 24 hours: Draw warning TBB p mount contains actions open, severe liker damage may occur? a chall taker more than 4, BBB and of actions implement 24 hours within Claker more than 5 dones in 24 hours a taker with other drugs pointed into action imple in a shall have 3 or more absorbed, drifted every day white using this product. Allways wint & external pointed or the every day white using this product. Allways wint & external pointed or may cause severe side machine, Symptoms may lackable: a side medically a blother in sinch If a side macked occur, stop use and seek medical help right away. Show throat warning IT see throat is severe, perside for more than 2 days, is accompanied or is lived by there; bestiache, main, sources, or worn titing, consult a doctor principly. If a site meeting occurs, step use and seek medical help digit away. Sees the value ording it som throat to severe, persists for more than 2 days, is accompanied or followed by treet headsche, costs, souses, or vara filing, consult a doctor promptly. Donetuse contecture — with any other drug containing as risminophen prescription or maprescription). If you are not sure whether a drug contains asselmently ten, ask adoctor or pharmacist. — if you are not leiting a prescription monocamine coldinars in his bor (MACG) giverbain dauge for depression, psychiatric, or encolosal conditions, or Parkinson's description drug a very contains and the product of the product o Do notices with any other drug containing acetaminophen ignescription or nonprescription; if you are not our whether a drug contains carthurinophen, each a decrease or pharmacist. If you are now taking a precorption monounine collaber in this for (MACI) (certain drugs the depression, pepthalinin, or transland conditions, or Paulimon's disease), or for 2 weeks other stopping the MACI drug. If you do not have if your precorption drug contains an MACI, each a decire or pharmacist better being his product. If you have ever had an allergic reaction to this product or any of its ingredients. in type time elem tour an attract reaction to the product or any of its righedent. Also a facolor before use if you have in the ridbease in high blood pressure in type didease in disheles in glacoma is outply that occan with too much pringing increal in a brushing problem such as emphysima or charaks bronchitis in house unimating due to an a harged proctate gland in pentisher or charaks outply as occans with snoking, authora, or emphysiema. In 2003 in medital didel Ask a destor before use If you have • Prorr disease • heart disease • thyroid disease ad labeltas a high billood pressue: a trouble unhalling due to san enkarged prodotte ghand an cough that course with too mach philisipa (incusus) a partial tent or divonic cough such as occurs with sanoking, authena, chronic branchilla, Ask a doctor or pharmacist before use if yet are a taking seddives or tranquitizers — a taking the blood this sing drug wortarth Ask a doctor or pharmaelist before use If you are taking the blood thinning drug warfarin When exting this predict a done-true men than divocal a existability may occur, especially in children a ranked divochileza may occur a a oxid alcoholic citiniu a be careful when driving a mactor whiche or operating mac til any a zbohol, sedelives, and branquilizers may increase choseshess When esing his product do not ese mere than directed Stop use and ask a deator if m you get nervous, dizzy or sleepless pais, near largestion or cough gets worse or keets more than 5 days (children) or 7 days (adults) tever gets worse or keets more than 3 days Step use and ask a doubtr if you get nervous, dany or sit epiess m redness or swelling is present m new symptoms occur wy upon revival, usay in ser pains pain, mass ingression, or cough gets wome or leafs more than 7 days lever gets worse or leafs more than 3 days in redness or swelling is present in a few paymptoms occur or cough comes back or occurs will need or headackle that leafs. These could be signs of a serious condition. cough comes back or occurs with rash or headashe that lasts. These could be signs of a serious condition. If programs or breast-feeding, ask a health professional before use. Naup out of mash of obtidizion. Overdose winning in case of overdose, get medical high or contact a Polson Control. Center sight every (1-504-522-1222), Grick medical attention is critical for adults as well as for children even if you do not notice any signs or operations. Eproguest or knest-beding, sik a health professional before use. Kaip out of reselv of children. Overdose warning: thicase of overdose, get medical help or contact a Polson Control Center right away (1-600-222-1222). Osist medical attention to ortical for adults as well as bot children event if you do not adult a significant or symptoms. Directions It like only as directed — see Overlose warring to keep use the doze copprovided — at and exceed 4 dozes per 24 has adults 8 c kildren 12 yas 8 over — 30 mil. every 4 has was a doctor ■ 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 mil. every 4 hrs children 6 to under 12 yrs 15 mil. every 4 hrs children 6 to under 12 yrs



children 4 lb under 12 yrs dradgen under 4 yrs

Questions or comments?1-111-4250

water, secretarin so solution, secretose

do not use

m seek 30 mL centains: sodium 44 mg m store at: 20-25°C §8-77°F)

Inactive ingredients aixeled, whydrous other acid, DeC yellow \$10, edebte daxdum, FDLE grees \$3, FDLE yellow \$6, taxot, glyceth, proplyine glycal, purified wate, accelario sodium, sodium bezzele, acclum chloride, acclum cirata, porbitol

children 4 lb under 6 yrs

store at 28-25°C (68-77°F). Do not retrigerate.

Questions or comments? 1-800-719-9299

do net use

Imarctive ingredientis buyated hydrogenisole, edetate discis im FDIC yellow FE town, giperin, mertral, monatosis sodium prospitale, polyetnyte e glycol, propiene glycol, purified water, sectival e sodium, sucrose, santtan gem

children under 4 yrs

SOUND BODY DAYTIME COLD AND FLU RELIEF NIGHTTIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate, guaifenesin, phenylephrine hcl kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50594-200

Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50594-200-	1 in 1 CARTON; Type 0: Not a Combination	07/08/2021	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	355 mL
Part 2	1 BOTTLE	355 mL

Part 1 of 2

SOUND BODY COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl solution

Product Information

 Item Code (Source)
 NDC:50594-123

 Route of Administration
 ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength 650 ma ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN in 30 mL **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) **DEXTROMETHORPHAN** 20 mg **HYDROBROMIDE** (DEXTROMETHORPHAN - UNII:7355X3ROTS) in 30 mL DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE -12.5 mg DOXYLAMINE SUCCINATE UNII:95QB77JKPL) in 30 mL PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -PHENYLEPHRINE 10 mg UNII:1WS297W6MV) **HYDROCHLORIDE** in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	GREEN	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

ı	P	ackaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:50594-123- 40	355 mL in 1 BOTTLE; 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		

Part 2 of 2

SOUND BODY COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

Product Information	
Item Code (Source)	NDC:50594-016
Route of Administration	ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg in 15 mL	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 15 mL	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL	

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

Product Characteristics		
Color	ORANGE (clear)	Score
Shape		Size
Flavor	FRUIT, MENTHOL	Imprint Code
Contains		

l	Packaging						
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
l		NDC:50594-016- 40	355 mL in 1 BOTTLE; 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						

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part341	07/08/2021				

Labeler - Big Lots Stores, Inc. (017885351)

Revised: 11/2022 Big Lots Stores, Inc.