#### DG HEALTH DAY TIME SEVERE COLD AND FLU RELIEF NIGHT TIME SEVERE COLD AND FLU RELIEF- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, doxylamine succinate Dolgencorp, LLC

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.

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# Dolgencorp, LLC Day Time Severe Cold & Flu Relief Night Time Severe Cold & Flu Relief Drug Facts

## Active ingredients (in each caplet) Daytime

Acetaminophen 325mg Dextromethorphan HBr 10mg Guaifenesin 200mg Phenylephrine HCl 5mg

## Purpose

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

## Uses

temporarily relieves common cold/flu symptoms:

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

#### 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

- thyroid disease
- diabetes
- liver disease
- heart disease
- 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 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
- do not exceed 8 caplets per 24 hrs

adults & children 12 yrs & over	2 caplets with water every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

## Other information

- each caplet contains: sodium 3 mg
- store at 20-25°C (68-77°F)

#### Inactive ingredients

croscarmellose sodium, crospovidone, FD&C yellow #6 aluminum lake, flavor, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, silicon dioxide, stearic acid, sucralose, talc, titanium dioxide

## **Questions or comments?**

1-888-309-9030

# Active ingredients (in each caplet) Nighttime

Acetaminophen 325 mg Dextromethorphan HBr 10 mg Doxylamine succinate 6.25 mg Phenylephrine HCl 5 mg

## Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

## Uses

temporarily relieves common cold/flu symptoms:

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

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

# 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
- do not exceed 8 caplets per 24 hrs

adults & children 12 yrs & over	2 caplets with water every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

#### Other information

• store at 20-25°C (68-77°F)

#### Inactive ingredients

crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, FD&C yellow #6 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, silicon dioxide, stearic acid, sucralose, talc, titanium dioxide

#### Questions or comments?

1-888-309-9030

# Package/Label Principal Display Panel

Compare to the active ingredients of Vicks<sup>®</sup> DayQuil<sup>®</sup> Severe+ VapoCOOL<sup>m</sup> and Vicks<sup>®</sup> NyQuil<sup>®</sup> Severe+ VapoCOOL<sup>m</sup>

Maximum Strength

Day Time Severe Cold & Flu Relief

Acetaminophen, Phenylephrine HCl

Dextromethorphan HBr, Guaifenesin

Pain Reliever, Fever Reducer, Nasal Decongestant

Cough Suppressant, Expectorant

Vapor Ice<sup>™</sup>

- Minor Aches & Pains, Fever
- Nasal Congestion & Sinus Pressure
- Cough
- Chest Congestion

16 Caplets

Non Drowsy

Actual Caplet Size

Maximum Strength

Night Time Severe Cold & Flu Relief

Acetaminophen, Phenylephrine HCl

Doxylamine Succinate, Dextromethorphan HBr

Pain Reliever, Fever Reducer, Nasal Decongestant

Antihistamine, Cough Suppressant

Vapor Ice<sup>™</sup>

- Minor Aches & Pains, Fever - Nasal Congestion & Sinus Pressure

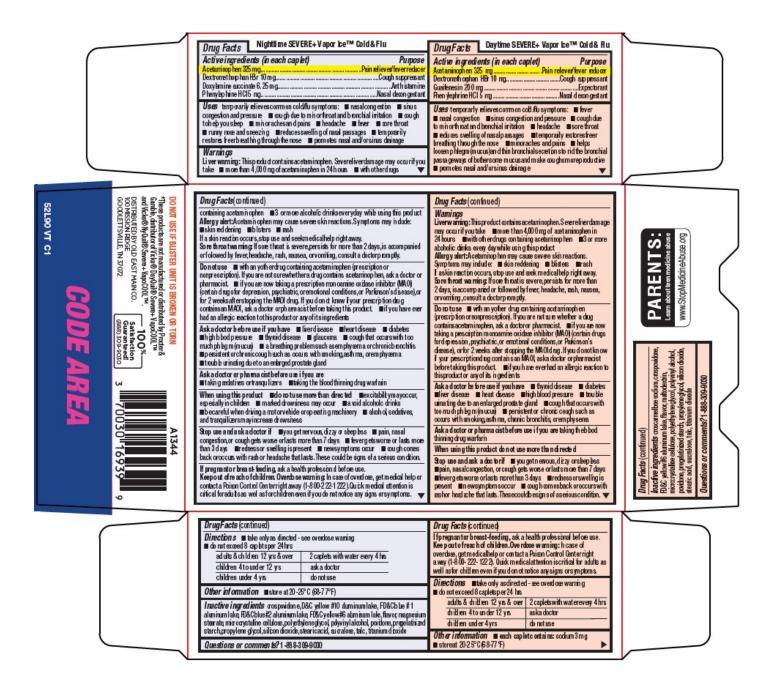
- Sneezing, Runny Nose

- Cough

8 Caplets

Actual Caplet Size





## DG HEALTH DAY TIME SEVERE COLD AND FLU RELIEF NIGHT TIME SEVERE COLD AND FLU RELIEF

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, doxylamine succinate kit

Product Information							
Р	Product Type         HUMAN OTC DRUG         Item Code (Source)         NDC:55910-643						
Packaging							
#	ltem Code	Package Descriptio	on	Marketing Start Date	Marketing End Date		
1	NDC:55910-643- 90	1 in 1 CARTON; Type 0: Not a Combination Product		05/26/2021			

Quantity of Parts						
Part #	Package Quantity	Total Product Quantity				
Part 1	8 BLISTER PACK	16				
Part 2	4 BLISTER PACK	8				

# Part 1 of 2

# DG HEALTH DAY TIME SEVERE COLD AND FLU RELIEF

NDC:55910-432

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride tablet, film coated

#### **Product Information**

Item Code (Source)

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

#### **Inactive Ingredients**

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
Dreduct Characteristics	

Color	ORAN	NGE	Score		no score	
Shape	OVAL	<u> </u>	Size		19mm	
Flavor			Imprint Code		L35C	
Contains						
Packaging						
# Item Code	Pa	ckage Descri	ption	Marketing Start Date		eting End Date
<b>1</b> NDC:55910-432- 2 00 Pr	in 1 BLISTER roduct	PACK; Type 0: No	ot a Combination			
Marketing In	nformat	ion				
Marketing Category	Applica	tion Number o Citation		Marketing Start Date		eting End Date
OTC monograph final	part341					
Part 2 of 2						
<b>NIGHT TIME</b> acetaminophen, d	lextrometh	orphan hydrob		<b>EF</b> ine succinate, phe	enylephrin	e
<b>NIGHT TIME</b> acetaminophen, d hydrochloride tabl	lextrometh et, film coa	orphan hydrob			enylephrin	e
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NIGHT TIME acetaminophen, d hydrochloride tabl Product Inform Item Code (Source Route of Administ Active Ingredien ACETAMINOPHEN (U DEXTROMETHORPHAN DOXYLAMINE SUCCI UNII:95QB77JKPL) PHENYLEPHRINE HY	extromethet, film coa et, film coa et, film coa et ation e) tration mt/Active Ingree NII: 36209ITL AN HYDROBI I - UNII: 7355X NATE (UNII: Y	orphan hydrok ted NDC:55910-725 ORAL Moiety dient Name _9D) (ACETAMINOI ROMIDE (UNII: 91 (3ROTS) V9B19B5Y12) (DOX	phen - Unii:36209iTi D2RTI9KYH) (YLAMINE -	Basis of St Basis of St Dextromethor Hydrobromide DoxyLamine SU	trength N RPHAN ICCINATE	<b>Strengt</b> 325 mg 10 mg
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NIGHT TIME acetaminophen, d hydrochloride tabl Product Inform Item Code (Source	extromethet, film coa et, film	orphan hydrok ted NDC:55910-725 ORAL Moiety dient Name -9D) (ACETAMINOI ROMIDE (UNII: 90 (3ROTS) V9B19B5Y12) (DOX DE (UNII: 04JA59T DE (UNII: 04JA59T DE (UNII: 684019 V5USQ3G) 8TBD)	promide, doxylam PHEN - UNII:362O9ITI D2RTI9KYH) (YLAMINE - TNSJ) (PHENYLEPHRIN	Basis of St Basis of St JOD) ACETAMINOPHEN DEXTROMETHOR HYDROBROMIDE DOXYLAMINE SU	trength N RPHAN ICCINATE E	Strengtl           325 mg           10 mg           6.25 mg           5 mg

FD&C YELLOW NO. 6 (UNII: H77/VEI93A8)       MAGNESIUM STEARATE (UNII: 70097M6I30)       MICROCRYSTALLINE CELULOSE (UNII: 70097M6I30)         MICROCRYSTALLINE CELULOSE (UNII: 70097M6I30)       POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDWAA)       POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDWAA)         POVIPONE, UNSPECIFIED (UNII: 3WQ0SDWAA)       POLYETHYLENE GLYCOL (UNII: 60C90167V3)       Image: Comparison of the compariso	ED&C YELLOW NO	<b>6</b> (IINIII ⊢	177\/FIQ3A8)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)       Image: Constant of the state		-	-				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 332059)90)       Image: Content of the conten				83206111)			
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532859)990)       Image: State of the state							
PVIDONE, UNSPECIFIED (UNII: FZ989GH94E)       Image: Comparison of the comparis				•			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3) SILICON DIOXIDE (UNII: ETI/72 6X8U4) STEARIC ACID (UNII: 4ELV72 65AP) SUCRALOSE (UMII: 96K6UQ3ZD4) TALC (UNII: 55K7J4R10) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) Product Characteristics Color GREEN Score no score Shape 0VAL Size 19mm Flavor U72V Contains 0VAL Size 19mm Flavor U72V Contains 0VAL Size 19mm Flavor U72V Contains 0VAL Size 19mm Flavor U72V Packaging # Item Code Package Description Marketing Start Date Date Date Date Date Date Date Dat							
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STEARIC ACID (UNII: 4ELV7265AP)       Image: Constraint of the second sec							
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Product Characteristics       GREEN       Score       no score         Shape       OVAL       Size       19mm         Imprint Code       L72V         Contains       Imprint Code       L72V         Value         Value       Size         Value       Imprint Code         Value       Imprint Code         Value       Value       Size         Value			IX9V2IP)				
GREEN       Score       no score         Sh→pe       OVAL       Size       19mm         Imprint Code       Imprint Code       1/2 V         Contains       Imprint Code       1/2 V         Package Description       Marketing Start Date       Marketing End Date         NDC:55910-725-       2 in 1 BLISTER PACK; Type 0: Not a Combination 00 Product       Marketing End Date         NDC:55910-725-       2 in 1 BLISTER PACK; Type 0: Not a Combination Product       Marketing Start Date       Marketing End Date         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing End Date			<b>,</b> ,				
GREEN       Score       no score         Sh→pe       OVAL       Size       19mm         Imprint Code       Imprint Code       1/2 V         Contains       Imprint Code       1/2 V         Package Description       Marketing Start Date       Marketing End Date         NDC:55910-725-       2 in 1 BLISTER PACK; Type 0: Not a Combination 00 Product       Marketing End Date         NDC:55910-725-       2 in 1 BLISTER PACK; Type 0: Not a Combination Product       Marketing Start Date       Marketing End Date         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing End Date							
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Labeler - Dolgencorp, LLC (068331990)

Revised: 12/2022

Dolgencorp, LLC