DG HEALTH COLD AND FLU RELIEF- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl 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.

Dolgencorp, LLC Cold & Flu Relief Drug Facts

Active ingredients (in each softgel) - Nighttime Cold & Flu

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

Active ingredients (in each softgel) - Daytime Cold & Flu

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purpose - Nighttime Cold & Flu

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Purpose - Daytime Cold & Flu

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses - Nighttime Cold & Flu

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- minor aches and pains
- sore throat
- headache
- runny nose and sneezing

Uses - Daytime Cold & Flu

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- minor aches and pains
- sore throat
- headache
- nasal congestion
- fever

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, lasts 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

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

Ask a doctor before use if you have - Daytime Cold & Flu

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

Ask a doctor or pharmacist before use if you are - Nighttime Cold & Flu

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

Ask a doctor or pharmacist before use if you are - Daytime Cold & Flu taking the blood thinning drug warfarin

When using this product - Nighttime Cold & Flu

- 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

When using the product - Daytime Cold & Flu do not use more than directed

Stop use and ask a doctor if - Nighttime Cold & Flu

- pain 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

Stop use and ask a doctor if - Daytime Cold & Flu

- 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 - Nighttime Cold & Flu

- take only as directed see overdose warning
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	2 softgels with water every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Directions - Daytime Cold & Flu

- take only as directed see overdose warning
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	2 softgels 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 - Nighttime Cold & Flu

D&C yellow no. 10, edible ink*, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution *may contain this ingredient

Inactive ingredients - Daytime Cold & Flu

edible ink*, FD&C red no. 40, FD&C yellow no. 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution *may contain this ingredient

Questions or comments?

1-888-309-9030

Package/Label Principal Display Panel

Compare to the active ingredients of Vicks[®] DayQuil[®] and Vicks[®] NyQuil[®] Cold & Flu Day Time

Cold & Flu Relief

Acetaminophen, Dextromethorphan HBr, Phenylephrine HCl

Pain Reliever, Fever Reducer, Cough Suppressant, Nasal Decongestant

Multi-Symptom Relief of:

- Aches, Fever, Sore Throat Nasal Congestion
- Cough Non-Drowsy

32 Softgels

Actual Softgel Size

Night Time

Acetaminophen, Dextromethorphan HBr, Doxylamine Succinate

Pain Reliever, Fever Reducer, Cough Suppressant, Antihistamine

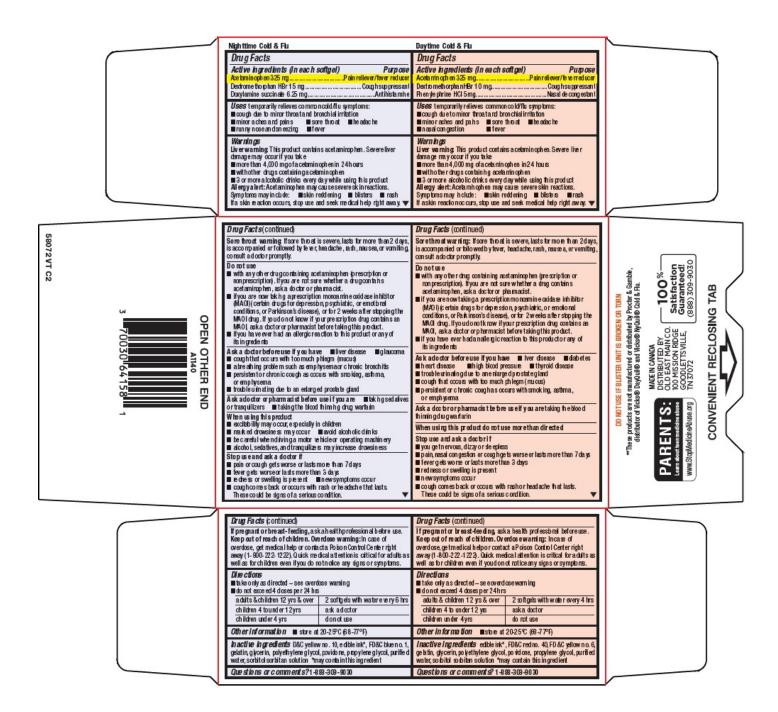
Multi-Symptom Relief of:

- Aches, Fever, Sore Throat
- Sneezing, Runny Nose Cough

16 Softgels

Actual Softgel Size





DG HEALTH COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55910-811

P	Packaging				
#	# Item Code Package Description		Marketing Start Date	Marketing End Date	
1	NDC:55910-811- 72	1 in 1 CARTON; Type 0: Not a Combination Product	06/20/2018		

Quantity of Parts				
Part #	Package Quantity	Total Product Quantity		
Part 1	8 BLISTER PACK	16		
Part 2	16 BLISTER PACK	32		

Part 1 of 2

DG HEALTH NIGHT TIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg		
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg		
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg		

Inactive Ingredients			
Ingredient Name	Strength		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			
SORBITAN (UNII: 6092ICV9RU)			

Product Characteristics				
Color	GREEN (clear)	Score	no score	
Shape	OVAL	Size	20mm	
Flavor		Imprint Code	056	
Contains				

Packaging

#	Code	Package Description	магкетіng Start Date	Marketing End Date
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

	Marketing Information				
Marketing Application Number or Monograph Category Citation			Marketing Start Date	Marketing End Date	
	OTC monograph final	part341			

Part 2 of 2

DG HEALTH DAY TIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information

Route of Administration ORAL

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

Inactive Ingredients			
Ingredient Name	Strength		
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			
SORBITAN (UNII: 6O92ICV9RU)			

Product Characteristics				
Color ORANGE Score no score				
Shape	OVAL	Size	20mm	
Flavor		Imprint Code	L994	

Contains

l	Pa	Packaging							
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
	1		2 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							

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph final	part341	06/20/2018					
J	P ** 12 12						

Labeler - Dolgencorp, LLC (068331990)

Revised: 4/2021 Dolgencorp, LLC