COLD AND FLU DAYTIME/NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, and doxylamine succinate Kroger Company

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.

Cold and Flu Daytime/Nighttime

NightTime COLD & FLU

Drug Facts

Active ingredients (in each Softgel)	Purpose	
Acetaminophen 325 mg	Pain reliever / Fever reducer	
Dextromethorphan HBr 15 mg	Cough suppressant	
Doxylamine succinate 6.25 mg	Antihistamine	

Uses

temporarily relieves common cold/flu symptoms:

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

Warnings

Liver warning

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

- more than 8 softgels in 24 hrs, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily 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.
- to make a child sleep

Ask a doctor before use if you have

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema
- trouble urinating due to 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, & tranquilizers may increase drowsiness

Stop use and ask a doctor if

- 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 signs
 of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning

Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults & for children even if you do not notice any signs or symptoms.

Directions

- take only as directed see Overdose warning
- do not exceed 8 softgels per 24 hrs

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

Other information

• store at room temperature between 20-25 °C (68-77 °F)

Inactive ingredients

FD&C Blue #1, FD&C Yellow #10, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

Questions or comments

1-800-632-6900

DayTime COLD & FLU

Drug Facts

Active ingredients (in each Softgel)	Purpose
Acetaminophen 325 mg	Pain reliever / Fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- cough due to minor throat & bronchial irritation
- sore throat
- headache

- minor aches & pains
- fever

Warnings

Liver warning

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

- more than 8 softgels in 24 hrs, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily 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, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see 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.

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to 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 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 get worse or last 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

Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults & for children even if you do not notice any signs or symptoms.

Directions

- take only as directed see Overdose warning
- do not exceed 8 softgels per 24 hrs

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

Other information

store at room temperature between 20-25 °C (68-77 °F)

Inactive ingredients

FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

Questions or comments

1-800-632-6900

PRINCIPAL DISPLAY PANEL - Kit Carton

*Compare to active ingredients in Vicks® Dayquil™ and Vicks® Nyquil™ Cold & Flu Liquicaps™

NDC 30142-620-48

COLD & FLU

DayTime

Multi-Symptom Relief

Pain Reliever Fever Reducer Cough Suppressant Nasal Decongestant

Acetaminophen 325mg Dextromethorphan HBr 10mg Phenylephrine HCl 5mg

32 SOFTGELS

COLD & FLU

NightTime

Multi-Symptom Relief

Pain Reliever Fever Reducer Cough Suppressant Antihistamine

Acetaminophen 325mg Dextromethorphan HBr 15mg Doxylamine succinate 6.25mg

16 SOFTGELS

Questions or comments: 1	900-632-6900	duestions or comments:	1-900-935-900
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"This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicke" DayGull" and Vicke" NyGull" Cold & Flu.

Lot No.: Exp Date:

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Active ingredients (in each Soffgel) Drug Facts

DayTime cold & FLU

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*Compare to active ingredients in Vicks® Dayquit™ and Vicks® Nyquit™ Cold & Fiu Liquicaps™

COLD & FLU

DayTime

Multi-Symptom Relief

Pain Reliever Fever Reducer Cough Suppressant Nasai Decongestant

Acetaminophen 325mg Dextromethorphan HBr 10mg Phenylephrine HCI 5mg

COLD & FLU

NightTime

Multi-Symptom Relief

Pain Reliever Fever Reducer

Acetaminophen 325mg Dextromethorphan HBr 15mg Doxylamine succinate 6.25mg

> 16 SOFTGELS

32 SOFTGELS

COLD AND FLU DAYTIME/NIGHTTIME

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

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:30142-754

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:30142-754- 12	4 in 1 CARTON	05/01/2021		
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product			

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

Part 1 of 2

COLD AND FLU DAYTIME

acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride capsule, liquid filled

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety Basis of Strength Strength **Ingredient Name** Acetaminophen (UNII: 36209ITL9D) (Acetaminophen - UNII:36209ITL9D) 325 mg Acetaminophen **Dextromethorphan Hydrobromide** (UNII: 9D2RTI9KYH) Dextromethorphan 10 mg (DEXTROMETHORPHAN - UNII:7355X3ROTS) Hydrobromide Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (PHENYLEPHRINE -Phenylephrine 5 mg UNII:1WS297W6MV) Hydrochloride

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: 3MJQ0SDW1A)	
Povidone, Unspecified (UNII: FZ989GH94E)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0KO0R)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	ORANGE	Score	no score	
Shape	OVAL	Size	20mm	
Flavor		Imprint Code	786	
Contains				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part341	05/01/2021		

Part 2 of 2

COLD AND FLU NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, and 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	10 mg		
Doxylamine Succinate (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	Doxylamine Succinate	6.25 mg		

Inactive Ingredients			
Ingredient Name	Strength		
FD&C Blue NO. 1 (UNII: H3R47K3TBD)			
D&C Yellow NO. 10 (UNII: 35SW5USQ3G)			
Gelatin, Unspecified (UNII: 2G86QN327L)			
Glycerin (UNII: PDC6A3C0OX)			
Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A)			

Povidone, Unspecified (UNII: FZ989GH94E)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0KO0R)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	GREEN	Score	no score	
Shape	OVAL	Size	20mm	
Flavor		Imprint Code	787	
Contains				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH FINAL	part341	05/01/2021			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part341	05/01/2021		

Labeler - Kroger Company (006999528)

Revised: 3/2021 Kroger Company