

**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

<i>Active ingredients (in each Softgel)</i>	<i>Purpose</i>
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 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

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 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 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

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

COLD & FLU

NightTime

Multi-Symptom Relief

- Pain Reliever
- Fever Reducer
- Cough Suppressant
- Antihistamine

Acetaminophen 325mg
Dextromethorphan HBr 15mg
Doxylamine succinate 6.25mg

16
SOFTGELS

Daytime Cold & Flu	Nighttime Cold & Flu
<p>Dosing Facts</p> <p>Active ingredients (in each Solgel):</p> <ul style="list-style-type: none"> Acetaminophen 250 mg Dextromethorphan HBr 10 mg Pseudoephedrine HCl 30 mg <p>Pain relief / Fever reduction</p> <p>Purpose</p>	<p>Dosing Facts</p> <p>Active ingredients (in each Solgel):</p> <ul style="list-style-type: none"> Acetaminophen 250 mg Dextromethorphan HBr 10 mg Pseudoephedrine HCl 30 mg Phenylephrine HCl 10 mg <p>Pain relief / Fever reduction</p> <p>Purpose</p>
<p>Uses: Temporarily relieves common cold/flu symptoms.</p> <p>Warnings:</p> <ul style="list-style-type: none"> Do not take if you have taken 3 or more acetaminophen tablets in 24 hours. Do not take if you have taken 10 or more pseudoephedrine tablets in 24 hours. Do not take if you have taken 10 or more phenylephrine tablets in 24 hours. 	<p>Uses: Temporarily relieves common cold/flu symptoms.</p> <p>Warnings:</p> <ul style="list-style-type: none"> Do not take if you have taken 3 or more acetaminophen tablets in 24 hours. Do not take if you have taken 10 or more pseudoephedrine tablets in 24 hours. Do not take if you have taken 10 or more phenylephrine tablets in 24 hours.
<p>Directions: Take 1 Solgel every 4 hours, with or without food. Do not exceed 6 Solgels in 24 hours.</p> <p>Caution: Do not take if you are taking any other products containing acetaminophen, pseudoephedrine, or phenylephrine.</p>	<p>Directions: Take 1 Solgel every 4 hours, with or without food. Do not exceed 6 Solgels in 24 hours.</p> <p>Caution: Do not take if you are taking any other products containing acetaminophen, pseudoephedrine, or phenylephrine.</p>
<p>Other Information: This product contains acetaminophen. Severe liver damage has been reported in some people who have taken 3 or more acetaminophen tablets in 24 hours.</p> <p>Other Information: This product contains acetaminophen. Severe liver damage has been reported in some people who have taken 3 or more acetaminophen tablets in 24 hours.</p>	<p>Other Information: This product contains acetaminophen. Severe liver damage has been reported in some people who have taken 3 or more acetaminophen tablets in 24 hours.</p> <p>Other Information: This product contains acetaminophen. Severe liver damage has been reported in some people who have taken 3 or more acetaminophen tablets in 24 hours.</p>

*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademarks Vicks® DayQuil™ and Vicks® NyQuil™ Cold & Flu.

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CT3014262048 REV.00-012021

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
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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
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	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: 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
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	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