COLD AND FLU DAY, NIGHT- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl Walgreen Company

Walgreens 44-012013

Active ingredients (in each 15 mL) (Day)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer Cough suppressant Nasal decongestant

Uses

- temporarily relieves common cold and flu symptoms:
 - sore throat
 - nasal congestion
 - minor aches and pains
 - cough due to minor throat and bronchial irritation
 - headache
- temporarily reduces fever

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 the user has

- high blood pressure
- difficulty in urination due to enlargement of the prostate gland
- cough that occurs with too much phlegm (mucus)
- liver disease
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- heart disease
- diabetes
- thyroid disease

Ask a doctor or pharmacist before use if the user is

taking the blood thinning drug warfarin.

When using this product

do not exceed recommended dosage.

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, nasal congestion, or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- 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.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

do not take more than directed

- do not exceed 4 doses per 24 hours
- mL = milliliter
- only use the dose cup provided

adults and children 12 years and	30 mL every 4
over	hours
children 6 to under 12 years	15 mL every 4
criliaren o to anaer 12 years	hours
children under 6 years	do not use

Other information

- each 15 mL contains: sodium 13 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients

anhydrous citric acid, FD&C yellow #6, flavors, glycerin, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sodium metabisulfite, sodium saccharin, sorbitol, sucralose

Questions or comments?

1-800-426-9391

Active ingredients (in each 30 mL) (Night)

Acetaminophen 650 mg Dextromethorphan HBr 30 mg Doxylamine succinate 12.5 mg

Purpose

Pain reliever/fever reducer Cough suppressant Antihistamine

Uses

- temporarily relieves common cold and flu symptoms:
 - headache
 - minor aches and pains
 - sore throat
 - runny nose and sneezing
 - cough due to minor throat and bronchial irritation
- temporarily reduces 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, 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
- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- 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

Ask a doctor or pharmacist before use if you are

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

When using this product

- excitability may occur, especially in children
- avoid alcoholic beverages
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery

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.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not take more than directed
- do not exceed 4 doses per 24 hours
- mL = milliliter
- only use the dose cup provided
- adults and children 12 years and over: 30 mL every 6 hours
- children under 12 years: do not use

Other information

- each 30 mL contains: sodium 13 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients

anhydrous citric acid, FD&C blue #1, FD&C red #40, flavor, glycerin, high fructose corn syrup, polyethylene glycol 400, propylene glycol, purified water, sodium benzoate, sodium chloride, sodium citrate dihydrate, sodium saccharin, sucralose

Questions or comments?

1-800-426-9391

Principal display panel

DAY & NIGHT PACK

NDC 0363-1213-02

Walgreens

WALGREENS PHARMACIST RECOMMENDED[†]

Compare to the active ingredients in Vicks® DayQuil® Cold & Flu & Vicks® NyQuil® Cold & Flu^{††}

DAY Cold & Flu

ACETAMINOPHEN /

PAIN RELIEVER / FEVER REDUCER
DEXTROMETHORPHAN HBr /
COUGH SUPPRESSANT
PHENYLEPHRINE HCI /
NASAL DECONGESTANT

- Relieves headaches, fever, sore throat, minor aches
- & pains, cough
- Nasal congestion
- Ages 6 Years and Over

Menthol flavor

NIGHT Cold & Flu ACETAMINOPHEN /

PAIN RELIEVER / FEVER REDUCER DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT

DOXYLAMINE SUCCINATE / ANTIHISTAMINE

Relieves headaches, fever, sore throat, minor aches & pains, sneezing, cough

- Runny nose
- Ages 12 Years and Over Cherry flavor

2 - 12 FL OZ (355 mL) BOTTLES / TOTAL 24 FL OZ (710 mL)

DO NOT TAKE DAY AND NIGHT PRODUCTS AT THE SAME TIME

TAMPER EVIDENT: DO NOT USE IF PRINTED NECK WRAP IS BROKEN OR MISSING

PARENTS:

Learn about teen medicine abuse www.StopMedicineAbuse.org

Do Not Take Daytime and Nighttime Products at the Same Time.

†Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands.
††This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademark Vicks® DayQuil® Cold & Flu.
This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademark Vicks® NyQuil® Cold & Flu.

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W-2201-012013-02 50844 REV0323A01201302



COLD AND FLU DAY, NIGHT

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0363-1213

Pac	kaging	

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:0363-1213-	1 in 1 PACKAGE; Type 0: Not a Combination	11/14/2022	

Quantity of Parts

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

Part 1 of 2

COLD AND FLU DAY

acetaminophen, dextromethorphan hbr, phenylephrine hcl solution

Product Information

Item Code (Source) NDC:0363-9912

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	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL	

Inactive Ingredients	
Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	orange	Score	
Shape		Size	
Flavor	MENTHOL	Imprint Code	
Contains			

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:0363- 9912-02	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing In	formation		
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC Monograph Drug	M012	11/14/2022	

Part 2 of 2

COLD AND FLU NIGHT

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

Product Information	
Item Code (Source)	NDC:0363-9913
Route of Administration	ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 30 mL		
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL		
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL		

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		

Product Characteristics			
Color	red (maroon)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	tem Code Package Description		Marketing End Date
1	NDC:0363- 9913-02	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Application Number or Monogo Category Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	11/14/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	11/14/2022	

Labeler - Walgreen Company (008965063)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	manufacture(0363-1213) , pack(0363-1213)

Revised: 11/2023 Walgreen Company