#### COLD AND FLU DAYTIME, NIGHTTIME, MAXIMUM STRENGTH- acetaminophen, dextromethorphan hbr, doxylamine succinate, guaifenesin, phenylephrine hcl Walgreen Company

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#### Walgreens 44-640677-08

#### Active ingredients (in each caplet) (Daytime Severe Cold & Flu)

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

#### Purpose

Pain reliever/fever reducer Cough suppressant Expectorant Nasal decongestant

#### Active ingredients (in each caplet) (Nighttime Severe Cold & Flu)

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 and flu symptoms:
  - minor aches and pains
  - nasal congestion
  - headache
  - fever
  - sore throat
  - sinus congestion and pressure
  - cough due to minor throat and bronchial irritation
  - cough to help you sleep (Nighttime only)
  - runny nose and sneezing (Nighttime only)

- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive (Daytime only)

# Warnings

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- with other drugs containing acetaminophen
- more than 4,000 mg of acetaminophen in 24 hours
- 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

- if you have ever had an allergic reaction to this product or any of its ingredients
- 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
- diabetes
- high blood pressure
- glaucoma (Nighttime only)
- thyroid disease
- heart disease
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema (Daytime only)
- difficulty in urination due to enlargement of the prostate gland
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma,

chronic bronchitis, or emphysema (Nighttime only)

# Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers (Nighttime only)

## When using this product

- do not exceed recommended dosage
- excitability may occur, especially in children (Nighttime only)
- marked drowsiness may occur (Nighttime only)
- avoid alcoholic beverages (Nighttime only)
- be careful when driving a motor vehicle or operating machinery (Nighttime only)
- alcohol, sedatives, and tranquilizers may increase drowsiness (Nighttime only)

# Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- 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

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.

### Do not take DAYTIME and NIGHTTIME products at the same time.

### Directions

- do not take more than directed
- do not take more than 8 caplets of Daytime and Nighttime products in any 24-hour period
- adults and children 12 years and over: take 2 caplets with water every 4 hours
- children under 12 years: ask a doctor

### Other information

- each caplet contains: sodium 3 mg
- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

#### Inactive ingredients (Daytime only)

corn starch, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polysorbate 80, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

### Inactive ingredients (Nighttime only)

black iron oxide, corn starch, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

#### **Questions or comments?**

1-800-426-9391

#### **Principal Display Panel**

#### **DAY & NIGHT PACK**

NDC 0363-6406-22

#### Walgreens

Compare to the active ingredients in Vicks® DayQuil® Severe Cold & Flu and Vicks® NyQuil® Severe Cold & Flu<sup>††</sup>

DAYTIME	NIGHTTIME
Severe	Severe
Cold & Flu	Cold & Flu
ACETAMINOPHEN / PAIN RELIEVER /	ACETAMINOPHEN / PAIN RELIEVER /
FEVER REDUCER	FEVER REDUCER
DEXTROMETHORPHAN HBr / COUGH	DEXTROMETHORPHAN HBr / COUGH
SUPPRESSANT	SUPPRESSANT
GUAIFENESIN / EXPECTORANT	DOXYLAMINE SUCCINATE / ANTIHISTAMINE
PHENYLEPHRINE HCI / NASAL	PHENYLEPHRINE HCI / NASAL
DECONGESTANT	DECONGESTANT
Maximum Strength	Maximum Strength
<b>16</b> CAPLETS	8 CAPLETS
ACTUAL SIZE	ACTUAL SIZE

#### **24 TOTAL CAPLETS**

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

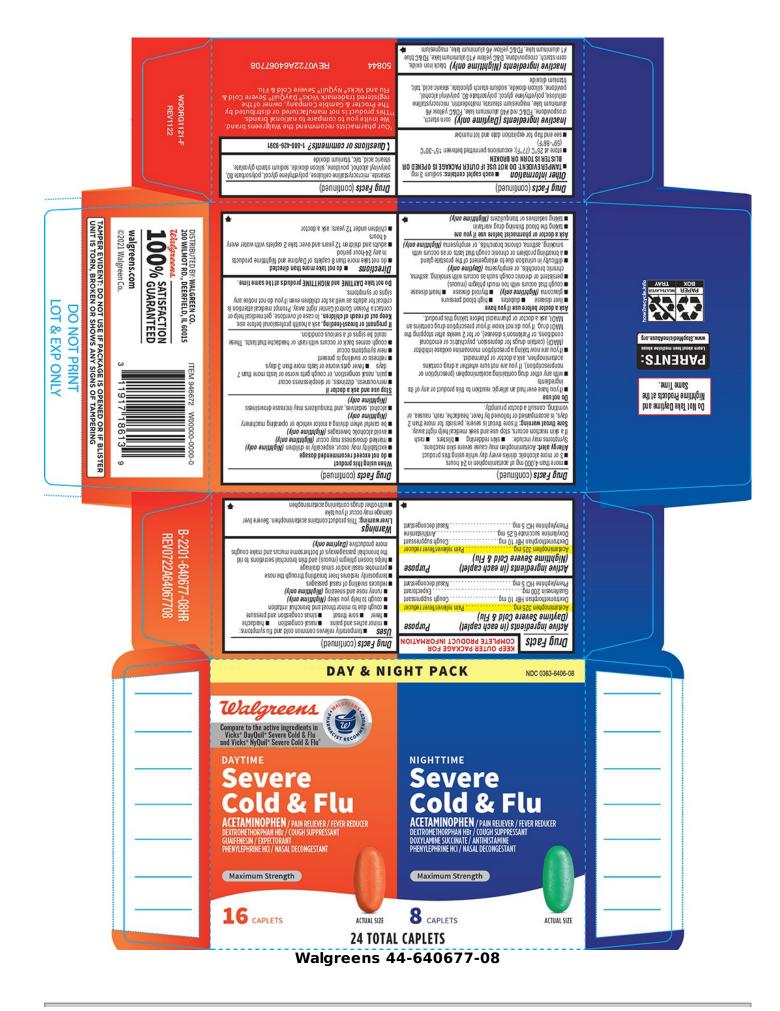
Do Not Take Daytime and

# Nighttime Products at the Same Time.

#### PARENTS: Learn about teen medicine abuse www.StopMedicineAbuse.org

<sup>†</sup>Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands. <sup>††</sup>This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademark Vicks® DayQuil® Severe Cold & Flu and Vicks® NyQuil® Severe Cold & Flu. 50844 REV0722A64067708

DISTRIBUTED BY: WALGREEN CO. 200 WILMOT RD., DEERFIELD, IL 60015 Walgreens 100 % SATISFACTION GUARANTEED walgreens.com © 2021 Walgreen Co.



# COLD AND FLU DAYTIME, NIGHTTIME, MAXIMUM STRENGTH

acetaminophen, dextromethorphan hbr, doxylamine succinate, guaifenesin, phenylephrine hcl kit

Produ	ıct Info	rmati	on					
Produc	ct Type		HUMAN OTC DRUG	1	ltem Code (Soເ	ırce)	NDC:036	63-6406
Packa	ging							
# Iten	n Code		Package Desc	riptic	on	Marketing Sta Date	art Ma	rketing End Date
1 NDC:0 6406-			PACKAGE, COMBINATION; nation Product	Туре С	): Not a	8/01/2015		
Quant	tity of F	Parts						
Part #		Pac	kage Quantity		Т	otal Product	Quantity	y
Part 1	2 BLISTE	r Pack			16			
Part 2	1 BLISTE	R PACK			8			
Part	1 of 2							
		E1 11	DAVTIME M					
			DAYTIME, M					
			<b>DAYTIME, M</b> romethorphan hbr, g				et, film co	pated
			-				et, film co	pated
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acetam Produ Route	ninopher ICt Info of Admir	n, dexti rmati nistrat	on ORAL				et, film co	oated
acetam Produ Route	ninopher ICt Info of Admir	n, dexti rmati nistrat	romethorphan hbr, g on				et, film co	oated
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Contains				
Flavor		Imprint Code	44;64	10
Shape 	OVAL	Size	19mr	
Color	orange	Score	no so	
Product Charact	eristics			
<b>FITANIUM DIOXIDE</b> (U	INII: 15FIX9V2JP)			
TALC (UNII: 7SEV7J4R1	U)			
STEARIC ACID (UNII: 4	ELV7Z65AP)	-		
SODIUM STARCH GLY	COLATE TYPE A PO	<b>TATO</b> (UNII: 5856J3G2A2)		
SILICON DIOXIDE (UN	II: ETJ7Z6XBU4)			
POVIDONE, UNSPECII	FIED (UNII: FZ989GH9	94E)		
POLYVINYL ALCOHOL		: 532B59J990)		
POLYSORBATE 80 (UN	•			
POLYETHYLENE GLYC	OL. UNSPECIFIED (	UNII: 3WOOSDW1A)		
MICROCRYSTALLINE	CELLULOSE (UNII: OF	P1R32D61U)		

# C	tem Code	Package Description	Marketing Start Date	Marketing End Date
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

# **Marketing Information**

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M012	02/27/2014	

# Part 2 of 2

# COLD AND FLU NIGHTTIME, MAXIMUM STRENGTH

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl tablet, film coated

## **Product Information**

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			
DEVTROMETHORDHAN HYDRORDONIDE /UNII: 0D30TI0/2/U					

DEXTROMETHORPHAN HTDROBROMIDE (UNII: 9D2RTI9RTH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	Strength
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
STARCH, CORN (UNII: 08232NY3SJ)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics						
Color	green	Score	no score			
Shape	OVAL	Size	19mm			
Flavor		Imprint Code	44;677			
Contains						

# Packaging

H	em ode	Package Description	Marketing Start Date	Marketing End Date
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information						
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
)12	08/01/2015					
ŀ	Application Number or Monograph Citation	Application Number or Monograph Citation Date				

# **Marketing Information**

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M012	08/01/2015	

# Labeler - Walgreen Company (008965063)

Establishment								
Name	Address	ID/FE	<b>Business Operations</b>					
LNK International, Inc.		832867837	7 manufacture	manufacture(0363-6406) , pack(0363-6406)				
Establishment								
Name	Ad	dress	ID/FEI	<b>Business Operations</b>				
LNK International, Inc.			832867894	manufacture(0363-6406)				
Establishment								
Name	Ad	dress	ID/FEI	<b>Business Operations</b>				
LNK International, Inc.			868734088	manufacture(0363-6406)				
Establishment								
Nama	<b>A</b> 4	duces		Business Onerstiens				

Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		117025878	manufacture(0363-6406)

Revised: 12/2023

Walgreen Company