DAYTIME NIGHTTIME COLD AND FLU RELIEF MULTI-SYMPTOMacetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl

P & L Development, 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.

Drug Facts

Active ingredients in Daytime (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Active ingredients in Nighttime (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

Purpose for Daytime

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Purpose for Nighttime

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Uses

DAYTIME

- temporarily relieves common cold and flu symptoms
 - cough due to minor throat and bronchial irritation
 - nasal condition
 - headache

- minor aches and pains
- fever
- sore throat

NIGHTTIME

- temporarily relieves common cold and flu symptoms
 - o cough due to minor throat and bronchial irritation
 - sore throat
 - headache
 - minor aches and pains
 - fever
 - runny nose & sneezing

Warnings

DAYTIME NIGHTTIME

Liver warning: These products contain 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

DAYTIME NIGHTTIME

- 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

DAYTIME

- liver disease
- heart disease

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

NIGHTTIME

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

Ask a doctor or pharmacist before use if you are

DAYTIME

• taking the blood thinning drug warfarin.

NIGHTTIME

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

When using this product,

DAYTIME

do not use more than directed.

NIGHTTIME

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

Stop use and ask a doctor if

DAYTIME

- nervousness, dizziness, or sleeplessness occur
- pain, cough, or nasal congestion gets worse or lasts more than 7 days
- redness or swelling is present
- new symptoms occur
- fever gets worse or lasts more than 3 days
- cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

NIGHTTIME

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.

DAYTIME NIGHTTIME

Overdose warning: Taking more than the recommended dose can cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

DAYTIME

- do not take more than directed (see Overdose warning)
- do not take more than 4 doses in 24 hours
- swallow whole: do not crush, chew, or dissolve
- adults and children 12 years and over: take 2 softgels with water every 4 hours
- children under 12 years: do not use

NIGHT TIME

- do not take more than directed (see Overdose warning)
- do not take more than 4 doses in 24 hours
- swallow whole: do not crush, chew, or dissolve
- adult and children 12 years and over: take 2 softgels with water every 6 hours
- children under 12 years: do not use

Other information

- store between 15°-30°C (59°-86°F)
- avoid excessive heat

Inactive ingredients

Daytime FD&C red #40, FD&C yellow #6, gelatin, glycerin, lecithin, light mineral oil, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol white ink

Nighttime D&C yellow #10, FD&C blue #1, gelatin, glycerin, lecithin, light mineral oil, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, white ink

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

when using daytime and nighttime products, carefully read the labeling to ensure correct dosing.

DAYTIME

non-drowsy

multi-symptom

day time

cold & flu relief

Acetaminophen 325 mg

dextromethorphan HBr 10 mg

phenylephrine HCl 5 mg

pain reliever/fever reducer

cough suppressant

nasal decongestant

alcohol-free

antihistamine-free

softgels**

(**liquid-filled capsules)

NIGHTTIME

Compare to the active ingredients in Vicks® DayQuil® and NyQuil®Cold & Flu LiquiCap®†

multi-symptom

night time

cold & flu relief

Acetaminophen 325 mg

dextromethorphan HBr 15 mg

doxylamine succinate 6.25 mg

pain reliever/fever reducer

cough suppressant

antihistamine

alcohol-free

softgels

(**liquid-filled capsules)

*This product is not manufactured or distributed by The Procter & Gamble Company, Vicks \$ DayQuil\$ and NyQuil\$ LiquiCaps \$ are registered trademarks of The Procter and Gamble Company.

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Distributed by:

PL Developments

200 Hicks Street

Westbury, NY 11590

Product Label

nonce sny signs or symptoms. JUGGICSI STEUDOU IS CLUDOSI JOL SONIES SS MAII SS JOL CUITOLAU BAAU IL ÀON DO DOL help or contact a Poison Control Center (1-800-222-1222) right away. Quick If pregnant or breast-feeding, sak a health professional before use. Keep out of reach of children. Overdose warming: Taking more than the recommended dose can cause liver damage. In case of overdose, get medical signs of a serious condition. tedness or swelling is present.
 new symbtoms occur.
 These could be redness or swelling is present. ■ fever gets worse or lasts more than 3 days ■ bein or cough gets worse or lasts more than 7 days Stop use and ask a doctor if ■ pe cereful when driving a motor vehicle or operating machinery alcohol, sedatives, and tranquilizers may increase drowsiness ■ wanked drowsiness may occur. ■ avoid alcoholic drinks excuspinty may occur, especially in children When using this product a do not exceed recommended dosage Ask a doctor or pharmacist before use if you are malking sedatives or tranquilizers m trouble uninating due to an enlarged prostate gland saprums' cynonic prouchyge' o' embplaaeuis s presigning bropiem o'r cyronic congly gyst jaste ancy se occura wyty amojoud'

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Ask a doctor before use if you have milver disease m glaucoma

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 Il you are now taking a prescription monoamine oxidase inhibitor (MAOI) sak a doctor or pharmacist.

■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen,

Drug Facts (continued) Nighttime Cold & Flu Softgel

Sore throat warning: If sore throat is severe, persists for more than 2 days, is

a or more alcoholic drinks every day while using this product

Cases . Frembousujá rejjeves common cold and flu symptoms:

occur if you take: more than 4,000 mg of acetaminophen in 24 hours

Liver warming: This product contains acetaminophen. Severe liver damage may

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в достот рготриу.

Warnings

Doxylamine succinate 6.25 mg

.gm 21 т8н пыфлофыт 15 mg.

Cold & Flu LiquiCaps®

multi-symptom

NDC 59726-901-24

medical attention is critical for adults as well as for children even if you do not help or contact a Poison Control Center (1-800-222-1222) right away, Quick If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children, Overdose warming: Taking more than the recommended dose can cause liver damage. In case of overdose, get medical

signs of a serious condition. ■ condit comes pack or occurs with rash or headache that lasts. These could be ■ redness or swelling is present ■ new symptoms occur ■ tever gets worse or lasts more than 3 days ■ pain, cough, or nasal congestion gets worse or lasts more than 7 days

uervousness, dizziness, or sieeplessness occur

nonce sult sidus or symptoms.

Mueu naing this product, do not exceed recommended dosage.

Ask a doctor or pharmacist before use if you are taking the blood thinning

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 trouble urinating due to an enierged proatate gland condip gust occurs with too munch byledim (mincure) aunssaud poold right ilver disease meart disease liver disease esse

Ask a doctor before use if you have pharmacist before taking this product.

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Drug Facts (continued) Daytime Cold & Flu Softgel

a doctor promptly. accompanied or followed by fever, headache, rash, nausea, or vomiting, consult accompanied or followed by fever, headache, rash, nausea, or vomiting, consult Include: m skin reddening m bilsters m rash if a skin reaction occurs, stop use and seek medical help nghit away. Sore throat wamning: if sore throat is severe, perisists for more than 2 days, is Allergy alert. Acelaminophen may cause severe sidin reactions. Symptoms may include:

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occur if you take: m more than 4,000 mg of acetaminophen in 24 hours Liver warming: This product contains acetaminophen. Severe liver damage may sbuimsN

■ cough due to minor throat and bronchial irritation ■ nasal congestion ■ fever ■ sone throat OSGS # pemporarily relieves common cold and flu symptoms:

Равнуврание НСІ 5 тд.

Cough suppressant Dextromethorphan HBr 10 mg. Active ingredients (in each soffgel) Purposes

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Drug Facts Daytime Cold & Flu Softgel

Active ingredients (in each softgel) Drug Facts Nighttime Cold & Hu Softgel Compare to the active ingredients in Vicks® DayQuil® and NyQuil®

night time

Acetaminophen 325 mg

dextromethorphan HBr 15 mg doxylamine succinate 6.25 mg

read incase

Cough suppressant

səsodınd

when using daytime and correct dosing.

nighttime products, carefully read the labeling to ensure

non-drowsy multi-symptom

cold & flu relief

Acetaminophen 325 mg dextromethorphan HBr 10 mg phenylephrine HCl 5 mg

nasal decongestant

alcohol-free antihistamine-free

pain reliever/fever reducer cough suppressant antihistamine alcohol-free

cold & flu relief

Distributed by:
PL Developments
200 Hicks Street
Westbury, NY 1159

8 softgels" ("liquid-filled capsules)

actual size

total 24 softgels

16 softgels" ("liquid-filled capsules)

EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER Street NY 11590

BROKEN OR SHOWS ANY TAMPER EVIDENT: UNIT IS TORN, I

Lot No.: Exp. Date:

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Total (59-86'F) asvoid excessive heat **Other information**■ shold excessive heat

■ shold excessive heat ■ adulfs and children 12 years and over; take 2 softgels with water every 4 hours ■ children under 12 years; do not use children under 12 years; do not use ■ adults and children 12 years and over: take 2 softgels with water every 6 hours swellow whole; do not crush, chew, or dissolve swallow whole; do not crush, chew, or dissolve ■ do not take more than 4 doses in 24 hours ■ do not take more than 4 doses in 24 hours m do not take more than directed (see Overdose warning) ■ do not take more than directed (see Overdose warming) Directions Directions Drug Facts (continued) Dung Facts (continued) Daytime Cold & Flu Softgel Nighttime Cold & Flu Softgel

READYinCASE Day Time Night Time Cold and Flu Relief

DAYTIME NIGHTTIME COLD AND FLU RELIEF MULTI-SYMPTOM

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59726-901

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:59726-901- 24	1 in 1 KIT; Type 0: Not a Combination Product	03/26/2021	

Ouantity of Parts

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

Part 1 of 2

NIGHT TIME COLD AND FLU RELIEF MULTI SYMPTOM

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Product Information

 Item Code (Source)
 NDC:59726-899

 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 (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POVIDONE (UNII: FZ989GH94E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SORBITAN (UNII: 6092ICV9RU)		
SORBITOL (UNII: 506T60A25R)		
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)		
LIGHT MINERAL OIL (UNII: N6K5787QVP)		
MANNITOL (UNII: 30WL53L36A)		

Product Characteristics				
Color	green	Score	no score	
Shape	OVAL	Size	21mm	
Flavor		Imprint Code	PC10	
Contains				

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1		8 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	03/26/2021	

Part 2 of 2

DAYTIME COLD AND FLU NON DROWSY

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information

Item Code (Source) NDC:59726-898

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

Inactive Ingredients		
Ingredient Name	Strength	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)		
LIGHT MINERAL OIL (UNII: N6K5787QVP)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POVIDONE (UNII: FZ 989GH94E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SORBITAN (UNII: 6O92ICV9RU)		
SORBITOL (UNII: 506T60A25R)		
MANNITOL (UNII: 30WL53L36A)		

Product Characteristics			
Color	orange	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	PC9
Contains	Contains		

Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1		16 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 final	part341	03/26/2021	
Maybating Information			
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/26/2021	

Labeler - P & L Development, LLC (800014821)

Revised: 12/2022 P & L Development, LLC