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
 - $\circ~$ 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

- 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 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

- 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

Daytime: adults and children 12 years and over: take 2 softgels with water every 4 hours

Nighttime: adults 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 butylated hydroxyanisole, butylated hydroxytoluene, carminic acid*, D&C yellow #10*, edible white ink, FD&C red #40*, FD&C yellow #6*, gelatin, glycerin, polyethylene glycol*, povidone, propylene glycol, purified water, sodium metabisulfite*, sorbitan*, sorbitol

*may contain this ingredient

Nighttime D&C yellow #10, edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan*, sorbitol

*may contain this ingredient

Questions or comments?

Principal Display Panel

DAYTIME

daytime

Multi-Symptom Cold & Flu Relief

acetaminophen (pain reliever / fever reducer)

dextromethorphan HBr (cough suppressant)

phenylephrine HCI (nasal decongestant)

- non-drowsy
- alcohol-free
- antihistamine

softgels**

(**liquid-filled capsules)

NIGHTTIME

nighttime

multi-symptom cold & flu relief

acetaminophen (pain reliever / fever reducer)

dextromethorphan HBr (cough suppressant)

doxylamine succinate (antihistamine)

alcohol-free

softgels

(**liquid-filled capsules)

When using Daytime and Nighttime products, carefully read the labeling to ensure correct dosing.

 $\texttt{+Compare to the active ingredients in Vicks <math display="inline">\circledast$ DayQuil \circledast and NyQuil \circledast Cold & Flu LiquiCaps \circledast

*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

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WOLLAWROOM TO COMPLETE WARMAND AND PRODUCT INFORMATION. TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BUSTERI UNIT 15 TORIN, BROKEN ON SKOWS ANY SKONS OF TAMPERING. "This product is not manufactured or distributed by The Procler & Gamble Company Vicket, DeyCall[®], MyOul[®], and Liqu/Cape[®] are registered trademarks of The Procler and Gamble Company. Questions or comments? Cuestions or comments? Call 1-811-753-3835 Monday-Friday 9AM-5PM EST Questions or comments? Inscribe Ingredients buryleated hydroxyanisate", buryleated wtor, FD8C yethow #5", getain, gytosm, polyethylene gytor, powidane, wtor, FD8C yethow #5", getain, gytosm, polyethylene gytor, powidane, wtor fD8C yethow #5", getain, gytosm, polyethylene gytor, powidane, wtor FD8C yethow #5", getain, gytosm, polyethylene gytor, powidane, wtor FD8C yethow #5", getain, gytosm, polyethylene gytor, polyethyl j**nacüve ingredients**. Disc yellow #10, editle mitte init. FD&c blue #1, gealit, giyceint, polyetirylene giycol, ponktone, propylene giycol, punified water, suchtenr, sochton - "mey contain this ingredient

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DAYTIME NIGHTTIME COLD AND FLU RELIEF MULTI-SYMPTOM

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Other information

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

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Product Information

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POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)Image: Subscription of the state of	GELATIN (UNII: 2G86QN	327L)				
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PROPYLENE GLYCOL (UNII: 6DC9Q167V3)Second State (UNII: 059QF0KUWATER (UNII: 059QF0KUSecond State (UNII: 6092USORBITOL (UNII: 506T0-25R)SORBITOL (UNII: 506T0-25R)Product CharacteristicsSoreNageScoreNo scoreShapeCAPSULESize	POLYETHYLENE GLYCO	DL, UNSPECIFIED (U	JNII: 3WJQOSDW1A)			
WATER (UNII: 059QF0KUSTER SORBITAN (UNII: 6092/USRU)SORBITAN (UNII: 506T2/SRU)SORBITOL (UNII: 506T2/SRU)Product Charact=sticsColororangeScoreno scoreShapeCAPSULESize20mm	POVIDONE (UNII: FZ989	GH94E)				
SORBITAN (UNII: 6092I/VPRU) SORBITOL (UNII: 506T6/A25R) Product Characteristics Color orange Score no score Shape CAPSULE Size 20mm	PROPYLENE GLYCOL (U	JNII: 6DC9Q167V3)				
SORBITOL (UNII: 506T-SERSTRIPTION OF STREEMENT OF STREE		· ·				
Product CharacteristicsColororangeScoreno scoreShapeCAPSULESize20mm						
ColororangeScoreno scoreShapeCAPSULESize20mm	SORBITOL (UNII: 506T60	DA25R)				
ColororangeScoreno scoreShapeCAPSULESize20mm						
Shape CAPSULE Size 20mm	Product Characte	eristics				
	Color	orange	Score	no score		
Flavor Imprint Code P19;95A;512;P19	Shape	CAPSULE	Size	20mm		
-	Flavor		Imprint Code	P19;95A;512;P19		

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1		32 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	12/31/2017	12/27/2024

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OTC monograph final	part341	12/31/2017	12/27/2024

Labeler - P & L Development, LLC (800014821)

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P & L Development, LLC