DAYTIME NIGHTTIME SEVERE COLD AND FLU RELIEF- acetaminophen dextromethorphan hbr guaifenesin phenylephrine hci doxylaminesucinate
P & L Development, LLC

Drug Facts

Active ingredients (in each 15 mL) DAYTIME

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Active ingredients for (in each 30 mL) NIGHTTIME

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Doxylamine Succinate 12.5 mg

Phenylephrine HCl 10 mg

Purposes for Day Time

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Purpose for Night Time

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

DAYTIME

- temporarily relieves common cold and flu symptoms
  - nasal congestion
  - sinus congestion and pressure

- minor aches and pains
- headache
- fever
- sore throat
- reduces swelling of nasal passages
- cough due to minor throat and bronchial irritation
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- help loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

NIGHTTIME

- temporarily relieves these common cold/flu symptoms
  - nasal congestion
  - sore throat
  - headache
  - sinus congestion and pressure
  - minor aches and pains
  - runny nose and sneezing
  - cough due to minor throat and bronchial irritation
- temporarily reduces
  - fever
  - cough to help you sleep
  - swelling of nasal passages
  - temporarily restores freer breathing through the nose
  - promotes nasal and/or sinus drainage

Warnings

DAYTIME

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

- adult takes more than 4 doses (30 mL each) of acetaminophen in 24 hours, which is the maximum daily amount
- child takes more than 4 doses (15 mL each) 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.

NIGHTTIME

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

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 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if you have

DAYTIME

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

NIGHTTIME

- liver disease
- heart disease
- thyroid disease
- high blood pressure
- diabetes
- glaucoma

- a sodium-restricted diet
- 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

DAYTIME

taking the blood thinning drug warfarin.

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

When using this product

DAYTIME

do not take more than directed

NIGHTTIME
- **do not take 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 and tranquilizers may increase drowsiness

Stop use and ask a doctor if

DAYTIME
- nervousness, dizziness or sleeplessness occur
- pain, nasal congestion, or cough gets worse, or lasts more than 5 days(children) or 7 days (adult)
- 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.

NIGHTTIME
- nervousness, dizziness, or sleeplessness occur
- pain or 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.

DAYTIME NIGHTTIME

Overdose warning: Taking more than the recommended dose (overdose) may couse 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

- **take only as directed (see Overdose warning)**
- do not take more than 4 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device.
- keep dosing cup with product
- mL= milliliter

adults and children 12 years and over	30 mL every 4 hours
children 6 to under 12 years	15 mL every 4 hours
children 4 to under 6 years	ask a doctor
children under 4 years	do not use

- **when using other Daytime or Night time products, carefully read each label to ensure correct dosing**

NIGHTTIME

- take only as directed (see Overdose warning)
- Do not exceed 4 doses per 24
- measure only with dosing cup provided. Do not use any other dosing device.
- mL= milliliter
- keep dosing cup with product
- adults and children 12 years and over: 30 mL every 4 hours
- children under 12 years of age: do not use

- **when using other Daytime or Nighttime products, carefully read each label or ensure correct dosing**

Other information

DAYTIME

- **each 15 mL contains:** sodium 12 mg

- store between 20-25ºC (68-77º). Do not refrigerate

NIGHTTIME
- **each 30 mL contains:** sodium 64 mg
- store between 20-25ºC (68-77ºF). Do not refrigerate

Inactive ingredients

Day Time

citric acid, FD&C yellow #6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride,sodium citrate, sorbitol, sucralose, xantham gum

Night Time

anhydrous citric acid, FD&C blue #1, Fd&C red #40, flavor, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, trisodium citrate dehydrate, sorbitol, sucralose, xanthan gum

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.

Compare to the active ingredients in **VICKS® DAYQUIL® and NYQUIL® Severe Cold & Flu***

DAYTIME

Severe

day time cold & flu relief

Acetaminophen 325 mg Pain Reliever / Fever Reducer

Dextromethorphan HBr 10 mg Cough Suppressant

Guaifenesin 200 mg Expectorant

Phenylephrine HCl 5 mg Nasal Decongestant

relieves:
- headache, fever, sore throat, minor aches & pains
- nasal/sinus congestion & sinus pressure
- Cough
- Chest congestion

For ages 6 years and over

max strength

non-drowsy

alcohol free

NIGHTTIME

maximum strength

severe

night time cold & flu relief

Acetaminophen 650 mg Pain Reliever / Fever Reducer

Dextromethorphan HBr 20 mg Cough Suppressant

Doxylamine Succinate 12.5 mg Antihistamine

Phenylephrine HCl 10 mg Nasal Decongestant

relieves:

- ache, fever, sore throat,
- cough
- Runny nose & sneezing
- nasal & sinus congestion

alcohol free

FL OZ (mL)

berry Flavor

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TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

Manufactured by:

PL Developments

11865 S. Alameda St

Lynwood, CA 90262

Product Label

READYinCASE Day Time Night Time Severe Cold and Flu Relief

DAYTIME NIGHTTIME SEVERE COLD AND FLU RELIEF

acetaminophen dextromethorphan hbr guaifenesin phenylephrine hci doxylaminesucinate kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49580-0813

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49580-0813-6	1 in 1 KIT; Type 0: Not a Combination Product	03/26/2021	03/28/2025

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	237 mL
Part 2	1 BOTTLE	237 mL

Part 1 of 2

SEVERE COLD AND FLU RELIEF DAYTIME

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid

Product Information

Item Code (Source)	NDC:49580-0415
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	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
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 15 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
GLYCERIN (UNII: PDC6A3C0OX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		237 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/26/2021	03/28/2025

Part 2 of 2

SEVERE COLD AND FLU NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hci liquid

Product Information

Item Code (Source)	NDC:49580-4160
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		237 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/26/2021	02/28/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/26/2021	03/28/2025

Labeler - P & L Development, LLC (101896231)

Revised: 4/2024 P & L Development, LLC