DAYTIME NIGHTTIME COLD AND FLU- acetaminophen dextromethorphan hbr phenylephrine hci doxylaminesucinate
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 each 15 mL) DAYTIME

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Active ingredients for (in each 30 mL) NIGHTTIME

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine Succinate 12.5 mg

Purposes for Day Time

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Purpose for Night Time

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Uses

DAYTIME

- temporarily relieves common cold and flu symptoms
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion

- fever
- cough due to minor throat and bronchial irritation

NIGHTTIME

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

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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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
- glaucoma
- 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 exceed recommended dosage.

NIGHTTIME

- 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

- 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

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

- **do not take more than 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

NIGHTTIME

- do not take more than directed (see Overdose warning)
- Do not take more than 4 doses in any 24-hours period
- 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 6 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:** potassium 5 mg
- **each 30 mL contains** sodium 24 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

acesulfame potassium, alcohol, anhydrous citric acid, FD&C blue #1, Fd&C red #40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium trisodium citrate dihydrate

Questions or comments?

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

Principal Display Panel

non-drowsy daytime

cold & flu relief

acetaminophen

(pain reliever / fever reducer)

dextromethorphan HBr

(cough suppressant)

phenylephrine HCl

(nasal decongestant)

- for ages 6 years & over
- alcohol-free
- antihistamine-free

nighttime

cold & flu relief

acetaminophen

(pain reliever / fever reducer)

dextromethorphan HBr

(cough suppressant)

doxylamine succinate

(antihistamine)

cherry flavor

- for ages 12 years & over
- alcohol 10%

FL OZ (mL)

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

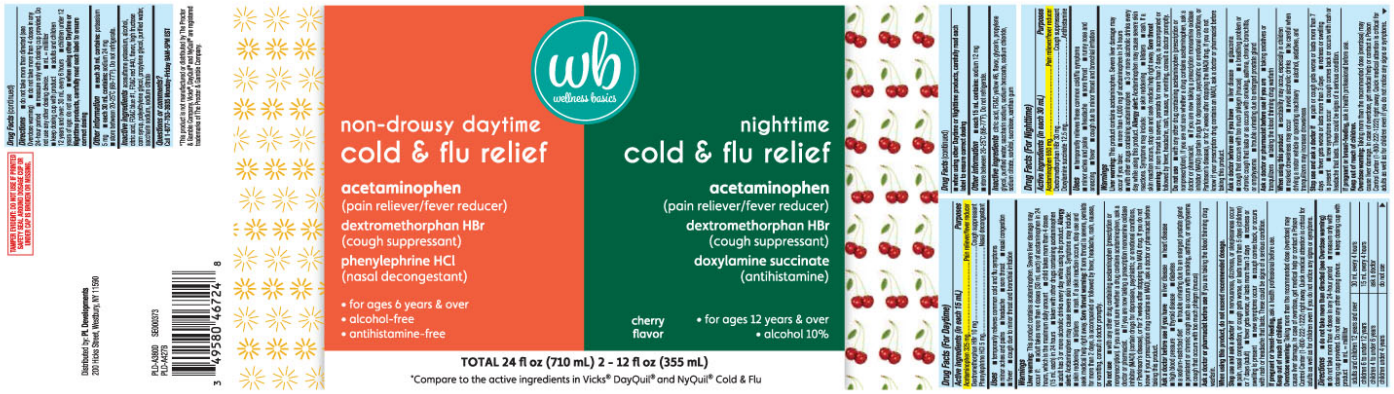
*This product is not manufactured or distributed by The Procter & Gamble Company. Vicks®, DayQuil® and NyQuil® are registered trademarks of The Procter & Gamble Company.

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

Distributed by: **PL Developments**

200 Hicks Street, Westbury, NY 11590

Product Label



WELLNESS BASICS Daytime Nighttime Cold and Flu Relief

DAYTIME NIGHTTIME COLD AND FLU

acetaminophen dextromethorphan hbr phenylephrine hci doxylaminesucinate kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49580-0567

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49580-0567-4	1 in 1 KIT; Type 0: Not a Combination Product	01/31/2018	02/28/2025

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE	355 mL
Part 2	1 BOTTLE	355 mL

Part 1 of 2

DAYTIME COLD AND FLU

acetaminophen dextromethorphan hbr phenylephrine hci liquid

Product Information	
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

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		355 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 final	part341	01/31/2018	02/28/2025

Part 2 of 2

NIGHTTIME COLD AND FLU

acetaminophen dextromethorphan hbr doxylamine succinate liquid

Product Information

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ALCOHOL (UNII: 3K9958V90M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

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

Packaging

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1		355 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

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OTC monograph final	part341	01/31/2018	02/28/2025

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OTC monograph final	part341	01/31/2018	02/28/2025

Labeler - P & L Development, LLC (101896231)