# DAYTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid P & L Development, LLC

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# **Drug Facts**

# Active ingredients (in each 15 mL)

## Acetaminophen 325 mg

Dextromethoprhan HBr 10 mg

Phenlyephrine HCl 5 mg

#### **Purposes**

#### Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

#### Uses

- temporarily relieves these common cold/flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - fever
  - nasal congestion
  - cough due to minor throat and bronchial irritation

# **Warnings**

**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

**Allery 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 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.
- with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

#### Ask a doctor before use if you have

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

## Ask a doctor or pharmacist before use if

you are taking the blood thinning drug warfarin.

# When using this product,

do not exceed recommended dosage.

# Stop use and ask a doctor if

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

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

- do not take more than directed (see overdose warning)
- do not exceed 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 Day Time and Night Time products, carefully read each label to ensure correct dosing

#### Other information

- each 15 mL contains: sodium 12 mg
- store between 20-25°C (68-77°F). Do not refrigerate

# Inactive ingredients

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

## **Questions or comments?**

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

# **Principal Display Panel**

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

# day time

#### Cold & Flu relief

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

pain reliever/fever reducer

cough suppressant

nasal decongestion

#### Relieves:

- aches
- fever
- sore throat
- cough
- nasal congestion

alcohol free

non-drowsy

antihistamine-free

for ages 6 years and over

FL OZ (mL)

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

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

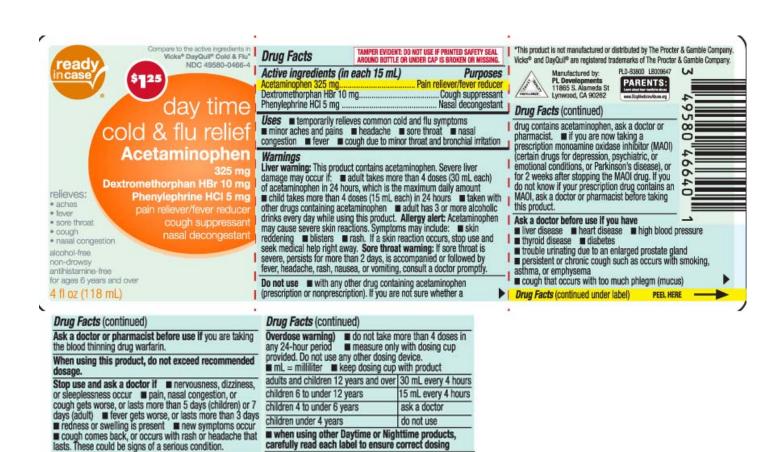
Manufactured by:

PL Developments

11865 S. Alameda St

Lynwood, CA 90262

# Package Label



#### **READYINCASE Day Time Cold & Flu Relief**

Call 1-877-753-3935

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#### DAYTIME COLD AND FLU

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Directions on do not take more than directed (see

Keep out of reach of children.

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49580-0466
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
<b>Basis of Strength</b>	Strength		
ACETAMINOPHEN	325 mg in 15 mL		
DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL		
PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL		
	ACETAMINOPHEN  DEXTROMETHORPHAN HYDROBROMIDE PHENYLEPHRINE		

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

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:49580- 0466-6	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2015		
2	NDC:49580- 0466-1	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2015		
3	NDC:49580- 0466-2	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2015		
4	NDC:49580- 0466-4	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2015		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/30/2015	

# Labeler - P & L Development, LLC (101896231)

Revised: 4/2024 P & L Development, LLC