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

Drug Facts

Active ingredients (in each 15 mL)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

- 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
  - helps loosen phlegn (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make cough more productive

Warnings

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

- adult take 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
- blistere
- 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 is followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use
- 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
- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis, or emphysema
- a sodium restricted diet

Ask a doctor or pharmacist before use if user is

taking the blood thinning drug warfarin

When using this product

do not take more than directed.

Stop use and ask a doctor if
- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present

- 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 can cause serious 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 and for children even if you do not notice any signs or symptoms

Directions

- **take only as directed (see overdose warning)**
- do not take more than 4 doses in 24 hours
- measure only with dosing cup provided. Do not use any other dosing device
- mL = milliliter
- keep dosing cup with product
- **when using other Daytime or Nighttime products, carefully read each label to insure correct dosing**

adults and children12 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

Other information

- each 15 mL contains: sodium 12 mg
- store between 20-25ºC (68-77ºF). 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 ST

Principal Display Panel

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

Severe

day time Cold & Flu Relief

Acetaminophen 325 mg pain reliever/fever reducer

ACHES / FEVER / SORE THROAT

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

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

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

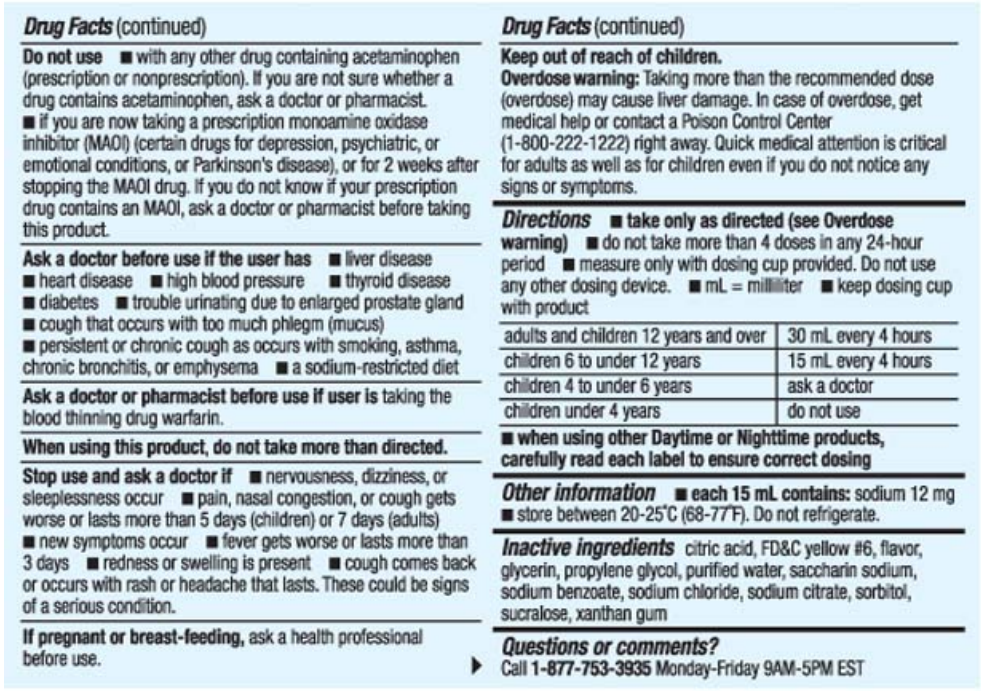
Manufactured by:

PL Developments

11865 S Alameda St

Lynwood, CA 90262

Product Label



READYinCASE Severe Day Time Cold & Flu Relief

SEVERE COLD AND FLU RELIEF DAYTIME

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**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
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 15 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49580-0415-8	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2021	

Marketing Information

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

Labeler - P & L Development, LLC (101896231)

Revised: 4/2024 P & L Development, LLC