NIGHTTIME SEVERE COLD AND COUGH- acetaminophen, diphenhydramine hcl, phenylephrine hcl liquid
P & L Development, LLC

Drug Facts

Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Diphenhydramine HCl 25 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer

Antihistamine/Cough suppressant

Nasal decongestant

Uses

- temporarily relieves there symptoms due to a cold
  - minor aches and pains
  - headache
  - sore throat
  - runny nose
  - sneezing
  - itchy, watery eyes due to hay fever
  - nasal and sinus congestion
  - itching of the nose or throat
  - cough due to minor throat and bronchial irritation
- temporarily reduces fever

Warnings

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

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

- to make a child sleepy
- 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 product containing diphenhydramine, even one used on skin
- 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
- glaucoma
- heart disease
- thyroid disease
- high blood pressure
- diabetes
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are taking

- the blood thinning drug warfarin
- sedatives or tranquilizers

When using this product

- **do not exceed recommended dosage**
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcohol drinks
- be careful when driving a motor vehicle or operating machinery
- marked drowsiness may occur
- excitability may occur, especially in children

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- 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 (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 take more than 6 doses (180 mL) in any 24-hour 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 4 hours
- children under 12 years of age; do not use

Other information

- **each 30 mL contains**: potassium 10 mg
- **each 30 mL contains**: sodium 14 mg
- store between 20-25ºC (68-77ºF). Do not refrigerate.

Inactive ingredients

acesulfame potassium, alcohol, citric acid, edetate disodium, FD&C blue #1, FD&C red #40, flavors, glycerin, maltitol, propylene glycol, purified water, sodium benzoate, sodium citrate

Principal Display Panel

Compare to the active ingredients in Theraflu® ExpressMax® Nighttime Severe Cold & Cough *

adult nighttime Severe Cold & Cough relief

Acetaminophen 650 mg

Pain reliever/Fever reducer

Diphenhydramine HCl 25 mg

Antihistamine/Cough Suppressant

Phenylephrine HCl 10 mg

Nasal decongestant

relieves:

- Nasal Congestion
- runny nose
- cough
- sore throat
- body ache
- Fever
- headache

for ages 12 years & older

alcohol 10%

berry flavor

FL OZ (mL)

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

*This product is not manufactured or distributed by GSK Consumer Health, distributor Theraflu® ExpressMax® Nighttime Severe Cold & Cough.

Manufactured by: PL Developments

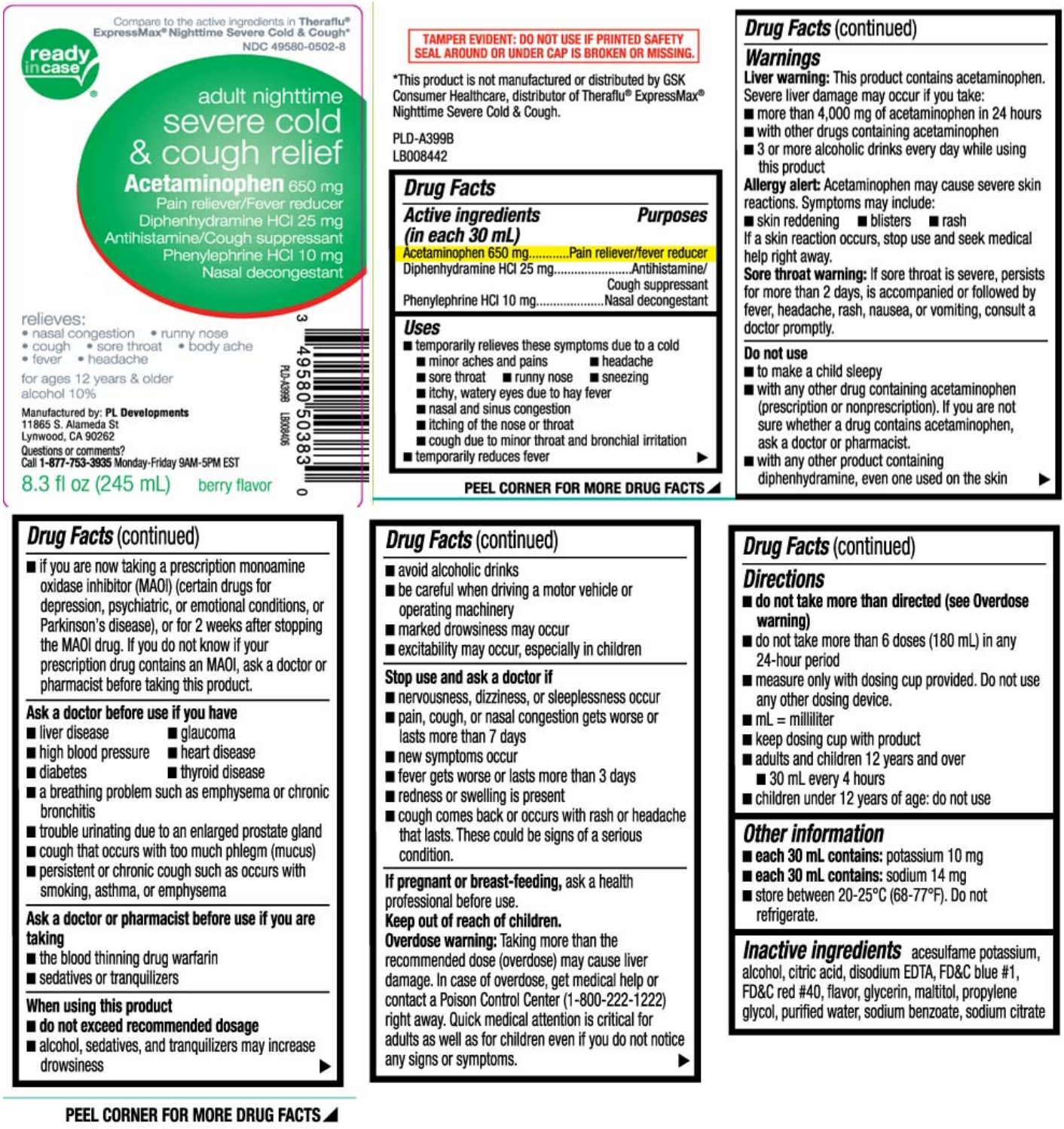
11865 S. Alameda ST

Lynwood, CA 90262

Questions or comments?

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

Product Label



READYinCASE Adult Night Time Severe Cold & Cough Relief Berry Flavor

NIGHTTIME SEVERE COLD AND COUGH

acetaminophen, diphenhydramine hcl, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49580-0502
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
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTITOL (UNII: D65DG142WK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49580-0502-8	245 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/30/2021	

Labeler - P & L Development, LLC (101896231)