FLU RELIEF THERAPY NIGHTTIME- acetaminophen, diphenhydramine hcl, phenylephrine hcl liquid
TOP CARE (Topco Associates 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 these symptoms due to a cold
  - minor aches and pains
  - headache
  - sore throat
  - runny nose
  - itchy, watery eyes
  - sneezing
  - nasal and sinus congestion
  - itching of the nose or throat
  - cough due to minor throat and bronchial irritation
- temporarily reduces fever

Warnings

Liver warnings: 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

- 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
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- 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 alcoholic 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 occurs
- 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 a 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 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 THERAFLU® NIGHTTIME SEVERE COLD & COUGH ACTIVE INGREDIENTS*

NIGHTTIME FOR ADULTS

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:

- Cough
- Itchy Bose or Throat

- Aches, Fever & Sore Throat
- Runny Nose & Sneezing
- Itchy, Watery Eyes
- Nasal Congestion

FOR AGES 12 +

Alcohol 10 %

CHERRY FLAVOR

FL OZ (mL)

*This product is not manufactured or distributed by GSK Consumer Healthcare, Inc., Distributor of Theraflu® Nighttime Severe Cold & Cough.

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

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007©TOPCO

QUESTIONS? 1-888-423-0139

topcare@topcare.comwww.topcarebrand.com

Product Label

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

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PLD-K265D
LB003434

Drug Facts

Active ingredients (in each 30 mL)	Purposes
Acetaminophen 650 mg	Pain reliever/fever reducer
Diphenhydramine HCl 25 mg	Antihistamine/ Cough suppressant
Phenylephrine HCl 10 mg	Nasal decongestant

Uses
- temporarily relieves these 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

PEEL CORNER FOR MORE DRUG FACTS

Drug Facts (continued)

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

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
- to make a child sleepy
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other product containing diphenhydramine, even one used on the skin
- if you are now taking a prescription monoamine

Drug Facts (continued)

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
- glaucoma
- high blood pressure
- heart disease
- diabetes
- thyroid disease
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- 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**
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- avoid alcoholic drinks

PEEL CORNER FOR MORE DRUG FACTS

Drug Facts (continued)
- 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.

Drug Facts (continued)

Directions
- **do not take more than directed (see Overdose warning)**
- do not take more than 6 doses (180 mL) in any 24-hour period
- keep dosing cup with product
- measure only with dosing cup provided. Do not use any other dosing device.
- mL = milliliter
- 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 20-25°C (68-77°F). Do not refrigerate.

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

TOPCARE HEALTH Severe Cold & Cough Relief

FLU RELIEF THERAPY NIGHTTIME

acetaminophen, diphenhydramine hcl, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-317
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	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-317-08	245 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/31/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	08/31/2015	

Labeler - TOP CARE (Topco Associates LLC) (006935977)