

**NIGHT TIME SEVERE COLD AND COUGH RELIEF- acetaminophen,
diphenhydramine hcl, phenylephrine hcl liquid
Chain Drug Consortium, LLC**

Drug facts Active ingredients

Active ingredients
(in each tablespoonful 15 mL)

Acetaminophen 325 mg
Diphenhydramine HCL 12.5 mg
Phenylephrine HCL 5mg

Purpose

Pain reliever/Fever reducer
Cough suppressant/Antihistamine
Nasal decongestant

Keep out of reach of children

Keep out of reach of children

Uses

temporarily relieves these common cold and flu symptoms:

- minor aches and pains
- headache
- sore throat
- nasal and sinus congestion
- runny nose
- sneezing
- itchy watery eyes
- itchy nose or throat
- cough due to minor throat and bronchial irritation as may occur with a cold
- temporarily reduces fever

Warnings

Liver warnings: This product contains acetaminophen.

Severe liver damage may occur if you take:

- more than 6 dose in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

Warnings

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

- 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 prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product
- with any other drug containing diphenhydramine, even one used on the skin
- for children under 4 years of age

Ask a doctor before use if you have

- liver disease
- heart disease
- thyroid disease
- high blood pressure
- diabetes
- trouble urinating due to an enlarged prostate gland
- a breathing problem or chronic cough that lasts or 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
- sedatives or tranquilizers

When using this product

- do not use more than directed (see overdose warning)
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcohol drinks
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
- redness or swelling is present
- symptoms do not get better within 7 days or are accompanied by a fever
- fever gets worse or lasts more than 3 days
- new symptoms occur
- cough lasts more than 7 days, comes back, or occurs with fever, rash or persistent headache. These could be signs of a serious condition.

If pregnant or breast feeding

ask a health professional before use.

Overdose warning

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact the Poison Control Center 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

Age	Dose
Children under 4 years	Do not use
Children 4 to under 12 years of age a doctor	Do not use unless directed by
Adults and children 12 years and over 4 hours	2 tablespoonful (30 mL) every
<ul style="list-style-type: none">• take only as recommended (see Overdose warning)• use dose cup or tablespoon (TBSP)• do not take more than 6 doses in any 24-hour period	

Other information

- each tablespoon (15 mL) contains: potassium 9 mg, sodium 6 mg
- dosage cup provided
- store between 20°-25° C (68°-77° F)
- do not refrigerate

Inactive ingredients

Acesulfame potassium, anhydrous citric acid, edetate disodium, FD and C Blue #1, FD and C Red #40, flavor, maltitol solution, propylene glycol, purified water, sodium benzoate

Questions?

Call weekdays from 9:30 AM to 4:30 PM EST at 1-877-798-5944

Product Label

NDC 6801-154-08

*COMPARE TO THE ACTIVE INGREDIENTS IN THERAFUL® WARMING RELIEF COLD AND CHEST CONGESTION

Premier Value®

Night Time Severe Cold and Cough Relief

Acetaminophen Pain Reliever/Fever Reducer
Diphenhydramine..... Antihistamine/Cough Suppressant
Phenylephrine HCL Nasal Congestion

Fever and Body Aches
Sore Throat
Headache
Nasal Congestion
Runny Nose
Cough

Cherry Flavor

8.3 FL OZ (245 mL)

PV Independently Tested Satisfaction Guaranteed

LF-007

DO NOT USE IF PRINTED SEAL UNDER AP IS TORN OR MISSING
Failure to follow these warnings could result in consequences

LB-007

DISTRIBUTED BY CHAIN DRUG CONSORTIUM
3301 NW BOCA RATON BLVD SUITE 101
BOCA RATON, FL 33431

Lot:

Exp:

*This product is not manufactured or distributed by Novartis Consumer Health Inc., owner of the registered trademark Theraflu® Night Time



NDC 68016-154-08

*COMPARE TO THE
ACTIVE INGREDIENTS
IN THERAFLU®

WARMING RELIEF NIGHT TIME
SEVERE COLD & COUGH

LF-007

Night Time Severe Cold & Cough Relief

Acetaminophen.....Pain Reliever
/Fever Reducer

Diphenhydramine..... Antihistamine
/Cough suppressant

Phenylephrine HCl.....Nasal Decongestant

- Fever & Body Aches
- Sore Throat
- Headache
- Nasal Congestion
- Runny Nose
- Cough

Cherry Flavor

8.3 FL OZ (245 mL)



DO NOT USE IF PRINTED SEAL UNDER
CAP IS TORN OR MISSING

Failure to follow these warnings could
result in serious consequences

Drug Facts

Active ingredients

Purpose

(in each tablespoonful, 15 mL)

Acetaminophen 325 mg.....

.....Pain reliever/Fever reducer

Diphenhydramine HCl 12.5 mg.....

.....Cough suppressant/Antihistamine

Phenylephrine HCl 5 mg.....

.....Nasal decongestant

LB-007

DISTRIBUTED BY
CHAIN DRUG CONSORTIUM
3301 NW BOCA RATON BLVD
SUITE 101
BOCA RATON, FL 33431



Lot:

Exp:

Drug Facts (continued)

Uses temporarily relieves these common cold and flu symptoms:

- minor aches and pains
- headache ■ sore throat
- nasal and sinus congestion
- runny nose ■ sneezing
- itchy watery eyes
- itchy nose or throat
- cough due to minor throat and bronchial irritation as may occur with a cold
- temporarily reduces fever

Warnings

Liver warning This product contains acetaminophen.

Severe liver damage may occur if you take:

- more than 6 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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 ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ▶

Drug Facts (continued)

- 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 diphenhydramine, even one used on skin
- for children under 4 years of age

Ask a doctor before use if you have

- liver disease
- heart disease ■ thyroid disease
- high blood pressure
- diabetes ■ glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem or chronic cough that lasts or 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
- sedatives or tranquilizers

When using this product

- **do not use more than directed (see overdose warning)**
- excitability may occur, especially in children ▶

Drug Facts (continued)

- marked drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
 - redness or swelling is present
 - symptoms do not get better within 7 days or are accompanied by a fever
 - fever gets worse or lasts more than 3 days
 - new symptoms occur
 - cough lasts more than 7 days, comes back, or occurs with fever, rash or persistent headache.
- 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 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** ■ take only as recommended (see Overdose warning)
- Use dosage cup or tablespoon (TBSP)
 - do not take more than 6 doses in any 24-hour period

Age	Dose
Children under 4 years of age	Do not use
Children 4 to under 12 years of age	Do not use unless directed by a doctor
Adults & children 12 years and over	2 tablespoonful (30 mL) every 4 hours

Other information

- each tablespoonful (15 mL) contains: potassium 9 mg, sodium 6 mg
- dosage cup provided
- store between 20-25°C (68-77°F)
- do not refrigerate

Inactive ingredients

Acesulfame potassium, anhydrous citric acid, edetate disodium, FD&C Blue #1, FD&C Red #40, flavor, maltitol solution, propylene glycol, purified water, sodium benzoate

Questions? Call weekdays from 9:30 AM to 4:30 PM EST at **1-877-798-5944**

* This product is not manufactured or distributed by Novartis Consumer Health Inc., owner of the registered trademark Theraflu® Night Time.

NIGHT TIME SEVERE COLD AND COUGH RELIEF

acetaminophen, diphenhydramine hcl, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-154
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
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 15 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

Inactive Ingredients

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

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY (CHERRY FLAVOR)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-154-08	245 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	10/04/2013	

Labeler - Chain Drug Consortium, LLC (101668460)

Registrant - AptaPharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(68016-154)

Revised: 12/2024

Chain Drug Consortium, LLC