

**SEVERE COLD AND COUGH RELIEF NIGHTTIME- acetaminophen,  
diphenhydramine hcl, phenylephrine hcl liquid  
H E B**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**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
  - sore throat
  - headache
  - runny nose
  - sneezing
  - itchy, watery eyes due to hay fever
  - nasal and sinus congestion
  - itchy 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

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, sedative, 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 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 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 20-25°C (68-77°F). 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

**Questions or comments?**

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

**Principal Display Panel**

Compare to Theraflu® Nighttime Severe Cold & Cough active ingredients\*

## NIGHTTIME

Severe Cold & Cough

Acetaminophen / Pain Reliever / Fever Reducer

Diphenhydramine / Antihistamine / Cough Suppressant

Phenylephrine HCl / Nasal Decongestant

Flu & Severe Cold

- Nasal Congestion,
- Fever,
- Cough,
- Sore Throat,
- Runny Nose,
- Headache,
- Body Ache

Alcohol 10%

For Ages 12 Years & Over

Cherry 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 of Theraflu® Nighttime Severe Cold & Cough.

MADE WITH PRIDE AND CARE FOR H-E-B® SAN ANTONIO, TX 78204

**Product Label**

Compare to **Theraflu® Nighttime Severe Cold & Cough** active ingredients\*

NDC 37808-017-08

**H-E-B**

NIGHTTIME  
**Severe Cold & Cough**

**Acetaminophen / Pain Reliever/Fever Reducer**  
**Diphenhydramine HCl / Antihistamine/Cough Suppressant**  
**Phenylephrine HCl / Nasal Decongestant**

**Flu & Severe Cold**

- Nasal Congestion • Fever
- Cough • Headache • Sore Throat
- Runny Nose • Body Ache

Alcohol 10%  
For Ages 12 Years & Over

**Cherry Flavor**

PLD-E265D LB005170  
**8.3 FL OZ (245 mL)**

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MADE WITH PRIDE AND CARE FOR H-E-B®, SAN ANTONIO, TX 78204

**H-E-B**

**100% GUARANTEE promise**

If you aren't completely pleased with this product, we'll be happy to replace it or refund your money. You have our word on it.

PLD-A265D  
LB005371  
8581-1710



**Drug Facts**

Active ingredients (in each 30 mL)	Purposes
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Diphenhydramine HCl 25 mg.....	Antihistamine/Cough suppressant
Phenylephrine HCl 10 mg.....	Nasal decongestant

PEEL CORNER FOR MORE DRUG FACTS

**Drug Facts (continued)**

**Uses**

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  - minor aches and pains
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**Drug Facts (continued)**

**Do not use**

- to make a child sleep
- 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 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
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- a breathing problem such as emphysema or chronic bronchitis
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**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

**Questions or comments?** Call toll free 1-877-753-3935 Monday-Friday 9AM-5PM EST

PEEL CORNER FOR MORE DRUG FACTS

**H-E-B Nighttime Severe Cold & Cough**

**SEVERE COLD AND COUGH RELIEF NIGHTTIME**

acetaminophen, diphenhydramine hcl, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-017
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 30 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

## Inactive Ingredients

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

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-017-08	245 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/31/2015	10/31/2025

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/31/2015	10/31/2025

**Labeler** - H E B (007924756)

