

FLU RELIEF THERAPY DAYTIME- acetaminophen, dextromethorphan hbr, 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.

Drug Facts

Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold
 - minor aches and pains
 - headache
 - nasal congestion
 - sore 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

- 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 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
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- 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.

When using this product,

do not exceed recommended dosage.

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, cough, or nasal congestion get worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with a fever, 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:** sodium 16 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, 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**

Principal Display Panel

Compare to TheraFlu® Daytime Severe Cold & Cough active ingredients*

DAYTIME

Severe Cold & Cough

Acetaminophen Pain Reliever / Fever Reducer

Dextromethorphan HBr Cough Suppressant

Phenylephrine HCl Nasal Decongestant

Flu & Severe Cold

- Nasal Congestion
- Fever
- Cough
- Sore Throat
- 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, Inc., distributor of Theraflu® Daytime Severe Cold & Cough

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

Questions or comments?

Call toll free 1-877-753-3935

Monday-Friday 9AM-5PM EST

Product Label

Compare to Theraflu® Daytime Severe Cold & Cough active ingredients*

NDC 37808-016-08

H-E-B

DAYTIME
Severe Cold & Cough

Acetaminophen / Pain Reliever/Fever Reducer
Dextromethorphan HBr / Cough Suppressant
Phenylephrine HCl / Nasal Decongestant

Flu & Severe Cold

- Nasal Congestion
- Fever
- Cough
- Sore Throat
- Headache
- Body Ache

Alcohol 10%
For Ages 12 Years & Over

Cherry Flavor

PLD-E264D LB005169
8.3 FL OZ (245 mL)

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

100% GUARANTEE promise

H-E-B

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-A264D
LB005370
8581-1710



Drug Facts

Active ingredients (in each 30 mL)	Purposes
Acetaminophen 650 mg.....	Pain reliever/fever reducer
Dextromethorphan HBr 20 mg.....	Cough suppressant
Phenylephrine HCl 10 mg.....	Nasal decongestant

PEEL CORNER FOR MORE DRUG FACTS

Drug Facts (continued)

Uses

- temporarily relieves these symptoms due to a cold
 - minor aches and pains
 - headache
 - nasal and sinus congestion
 - sore 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.

Drug Facts (continued)

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
- thyroid disease
- diabetes
- high blood pressure
- 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.

Drug Facts (continued)

When using this product, do not exceed recommended dosage.

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
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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: sodium 16 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 DayTime Severe Cold & Cough

FLU RELIEF THERAPY DAYTIME

acetaminophen, dextromethorphan hbr, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-016
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
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 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:37808-016-08	245 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/31/2016	12/31/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/31/2016	12/31/2025

Labeler - H E B (007924756)

