

SEVERE COLD AND COUGH DAYTIME- acetaminophen, dextromethorphan hbr, phenylephrine hcl liquid
TOP CARE (Topco Associates LLC)

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 gets 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 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

Principal Display Panel

COMPARE TO THERAFLU® DAYTIME SEVERE COLD & COUGH ACTIVE INGREDIENTS*

DAYTIME FOR ADULTS

Severe Cold & Cough Relief

ACETAMINOPHEN 650 mg PAIN RELIEVER • FEVER REDUCER

DEXTROMETHORPHAN HBr 20 mg COUGH SUPPRESSANT

PHENYLEPHRINE HCl 10 mg NASAL DECONGESTANT

RELIEVES:

- Cough
- Nasal Congestion
- Aches, Fever & Sore Throat

FOR AGES 12 +

CHERRY FLAVOR

Alcohol 10%

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 Novartis Consumer Health, Inc., distributor of Theraflu® Daytime Severe Cold & Cough

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ELK GROVE VILLAGE, IL 60007

QUESTIONS? 1888-423-0139

topcare@topco.com www.topcarebrand.com

Product Label

TopCare
health

NDC 36800-316-08

COMPARE TO
THERAFLU® DAYTIME
SEVERE COLD & COUGH
ACTIVE INGREDIENTS*

DAYTIME FOR ADULTS

Severe Cold & Cough Relief

ACETAMINOPHEN 650 mg
PAIN RELIEVER • FEVER REDUCER

DEXTROMETHORPHAN HBr 20 mg
COUGH SUPPRESSANT

PHENYLEPHRINE HCl 10 mg
NASAL DECONGESTANT

RELIEVES:
• Cough • Nasal Congestion
• Aches, Fever & Sore Throat

FOR AGES 12+

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QUESTIONS? 1-888-423-0139
topcare@topco.com www.topcarebrand.com
Visit here for more information:
http://topbrnds.com/48zq4

CHERRY FLAVOR

0 36800 22449 0
PLD-12640 LB003544

8.3 FL OZ (245 mL) Alcohol 10%

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 Healthcare, distributor of Theraflu® Daytime Severe Cold & Cough.

PLD-12640
LB003544

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

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

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

- 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

Drug Facts (continued)

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.

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)

- new symptoms occur
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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

Drug Facts (continued)

- 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

PEEL CORNER FOR MORE DRUG FACTS

TOPCARE HEALTH Severe Cold & Cough Relief

SEVERE COLD AND COUGH DAYTIME

acetaminophen, dextromethorphan hbr, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-316
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:36800-316-08	245 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/30/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	11/30/2015	

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

Revised: 10/2023

TOP CARE (Topco Associates LLC)