

SEVERE COLD AND COUGH RELIEF DAYTIME- acetaminophen, dextromethorphan hbr, phenylephrine hcl liquid

AmerisourceBergen (Good Neighbor Pharmacy) 46122

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 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*

ALCOHOL 10 %

FOR AGES 12 YEARS AND OVER

Adult Severe Cold & Cough Relief

DAYTIME

Pain Reliever / Fever Reducer (Acetaminophen)

Cough Suppressant (Dextromethorphan)

Nasal Decongestant (Phenylephrine)

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

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

Distributed by AmerisouceBergen

1300 Morris Drive, Chesterbrook, PA 19087

Questions or Concerns? Visit us at www.mygnp.com

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

Product Label



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

NDC 46122-336-33

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PLD-H264B
LB003544

Drug Facts (continued)

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

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ALCOHOL 10%
FOR AGES 12 YEARS AND OVER
Adult
**Severe Cold &
Cough Relief**

Daytime

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

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

Cherry Flavor

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8.3 fl oz (245 mL)



Drug Facts

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Dextromethorphan HBr 20 mg.....Cough suppressant
Phenylephrine HCl 10 mg.....Nasal decongestant

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PEEL CORNER FOR MORE DRUG FACTS ◀

Drug Facts (continued)

if your prescription drug contains an MAOI, ask a
doctor or pharmacist before taking this product.

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■ liver disease ■ heart disease
■ thyroid disease ■ diabetes
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■ cough that occurs with too much phlegm (mucus)
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Drug Facts (continued)

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■ keep dosing cup with product
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30 mL every 4 hours
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Other information

■ each 30 mL contains: sodium 16 mg
■ store between 20-25°C (68-77°F). Do not
refrigerate. ▶

Drug Facts (continued)

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 ◀

Good Neighbor Pharmacy Adult Severe Cold & Cough Relief Cherry

SEVERE COLD AND COUGH RELIEF DAYTIME

acetaminophen, dextromethorphan hbr, phenylephrine hcl liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:46122-336 |
| 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: HBR47K3TBD) | |
| 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:46122-336-33 | 245 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/31/2015 | 12/31/2020 |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part341 | 12/31/2015 | 12/31/2020 |

Revised: 12/2018

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