

COLD AND FLU DAYTIME RELIEF- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid
Freds Inc

Drug Facts

Active ingredients (in each 15 mL)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves common cold/flu symptoms:
 - minor aches and pains
 - headache
 - sore throat
 - fever
 - nasal congestion
 - cough due to minor throat and bronchial irritation

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 4 doses (30 mL each) of acetaminophen in 24 hours, which is the maximum daily amount
- child takes more than 4 doses (15 mL each) in 24 hours
- taken with other drugs containing acetaminophen
- adult has 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
- thyroid disease
- diabetes
- high blood pressure
- a sodium-restricted diet
- persistent or chronic cough such as occurs with smoking, asthma or emphysema
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if the user is

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 occurs
- pain, nasal congestion or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- fever gets worse, or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- 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 4 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device
- keep dosing cup with product
- mL=milliliter

adults and children 12 years and over	30 mL every 4 hours
children 6 to under 12 years	15 mL every 4 hours
children 4 to under 6 years	ask a doctor
children under 4 years	do not use

- **When using Day Time and Night Time products, carefully read each label to ensure correct dosing**

Other information

- **each 15 mL contains:** sodium 12 mg
- store between 20-25°C (68-77°F)
- do not refrigerate

Inactive ingredients

citric acid, FD&C yellow #6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol, sucralose, xanthan gum

Questions or comments?

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

Principal Display Panel

Compare to the active ingredients in Vicks® DayQuil® Cold & Flu*

DAYTIME RELIEF

Cold & Flu

Each dose (per 15 mL) of oral solution contains:

325 mg- Acetaminophen (Pain reliever/fever reducer)

10 mg- Dextromethorphan HBr (cough suppressant)

Phenylephrine HCl (Nasal decongestant)

- aches, fever and sore throat
- nasal congestion
- cough

Non-Drowsy • Multi-Symptom

Alcohol-Free • Antihistamine-Free

FL OZ (mL)

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

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DISTRIBUTED BY: fred's Inc

4300 NEW GETWELL RD, MEMPHIS, TN 38118

www.fredsinc.com

Package Label

fred's Pharmacy NDC 55315-066-12

Compare to the active ingredients in Vicks® DayQuil® Cold & Flu®

DAYTIME RELIEF Cold & Flu

Each dose (per 15 mL) of oral solution contains:
325 mg - Acetaminophen (Pain reliever/Fever reducer)
10 mg - Dextromethorphan HBr (Cough Suppressant)
5 mg - Phenylephrine HCl (Nasal Decongestant)

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

Non-Drowsy • Multi-Symptom
Alcohol-Free • Antihistamine-Free
For Ages 6 Years & Over

12 FL OZ (355 mL)

Drug Facts TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

Active ingredients (in each 15 mL)	Purposes
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses temporarily relieves common cold and flu symptoms
■ minor aches and pains ■ headache ■ fever ■ sore throat
■ nasal congestion ■ cough due to minor throat and bronchial irritation

Warnings
Liver warning: This product contains acetaminophen. Severe liver damage may occur if: ■ adult takes more than 4 doses (30 mL each) of acetaminophen in 24 hours, which is the maximum daily amount
■ child takes more than 4 doses (15 mL each) in 24 hours ■ taken with other drugs containing acetaminophen ■ adult has 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 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 ■ high blood pressure ■ thyroid disease
■ diabetes ■ a sodium-restricted diet
■ trouble urinating due to an enlarged prostate gland
■ persistent or chronic cough such 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.

When using this product, do not exceed recommended dosage.

Drug Facts (continued)

Stop use and ask a doctor if ■ nervousness, dizziness, or sleeplessness occur
■ pain, nasal congestion, or cough gets worse, or lasts more than 5 days (children) or 7 days (adult) ■ fever gets worse, or lasts more than 3 days ■ redness or swelling is present ■ new symptoms occur ■ 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 4 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 6 to under 12 years	15 mL every 4 hours
children 4 to under 6 years	ask a doctor
children under 4 years	do not use

■ when using other Daytime or Nighttime products, carefully read each label to ensure correct dosing

Other information ■ each 15 mL contains: sodium 12 mg
■ store between 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients citric acid, FD&C yellow #6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol, sucralose, xanthan gum

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

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4300 NEW GETWELL RD, MEMPHIS, TN 38118
www.fredsinc.com

PLD-C380D LB006287 SKU# 243591

100% satisfaction guaranteed
Questions or comments: 1-866-331-FRED (3733)

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www.StopMedicineAbuse.org

FRED'S PHARMACY Daytime Cold & Flu Relief

COLD AND FLU DAYTIME RELIEF

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-066
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
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-066-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/31/2015	07/31/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/31/2015	07/31/2024

Labeler - Freds Inc (005866116)