

DAYTIME COLD AND FLU- acetaminophen, dextromethorphan hbr liquid
CVS PHARMACY, INC

Drug Facts

Active ingredients (in each 15 mL)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Uses

- temporarily relieves these common cold/flu symptoms:
 - minor aches and pains
 - headache
 - 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:

- adult takes more than 4 doses (30 mL each) of acetaminophen in 24 hours, which is the maximum daily amount for this product
- child takes more than 4 doses (15 mL each) in 24 hours, which is the maximum daily amount for this product
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks everyday 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.
- if you are allergic to acetaminophen
- 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
- a breathing problem such as emphysema or chronic bronchitis
- 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 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

- pain, 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

DAYTIME

COLD & FLU

ACETAMINOPHEN 325 mg

Pain reliever; Fever reducer

DEXTROMETHORPHAN HBr 10 mg

Cough suppressant

MULTI-SYMPTOM RELIEF

Relieves:

Aches, Fever, Sore throat, Cough

No added alcohol

See New Drug Facts

FL OZ (mL)

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

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

Package Label

CVS Health.

NDC 51316-421-12

DAYTIME COLD & FLU

ACETAMINOPHEN

Pain reliever; Fever reducer

DEXTROMETHORPHAN HBr
Cough suppressant

MULTI-SYMPTOM RELIEF

Relieves: Aches, Fever,
Sore throat, Cough

No added alcohol

See New Drug Facts

12 FL OZ (355 mL)

PLD-A854A LB009907

Drug Facts

Active ingredients (in each 15 mL)

Acetaminophen 325 mgPain reliever/fever reducer
Dextromethorphan HBr 10 mgCough suppressant

Purposes

Uses

- temporarily relieves these common cold and flu symptoms
 - minor aches and pains
 - headache
 - cough due to minor throat and bronchial irritation
- temporarily reduces fever

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

PARENTS:

Learn about teen medicine abuse
www.StopMedicineAbuse.org

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PLD-A854A LB009917

PEEL CORNER FOR MORE DRUG FACTS

Drug Facts (continued)

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 for this product
 - child takes more than 4 doses (15 mL each) in 24 hours, which is the maximum daily amount for this product
 - 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 allergic to acetaminophen
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

PEEL CORNER FOR MORE DRUG FACTS

Drug Facts (continued)

- 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
- a breathing problem such as emphysema or chronic bronchitis
- 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.

Stop use and ask a doctor if

- pain 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.

Drug Facts (continued)

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

Drug Facts (continued)

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 no. 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

CVS HEALTH Daytime Cold & Flu

DAYTIME COLD AND FLU

acetaminophen, dextromethorphan hbr liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-421
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

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:51316-421-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/31/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/31/2024	

Labeler - CVS PHARMACY, INC (062312574)