

LEADER DAYTIME COLD AND FLU- acetaminophen, dextromethorphan hbr, phenylephrine hcl solution
Cardinal Health 110, LLC. dba Leader

Cardinal Health Daytime Cold & Flu Drug Facts

Active ingredients (in each 15 mL)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

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

Warnings

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

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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 use more than directed

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- 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: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- take only as directed – see Overdose warning
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 4 hrs
children 6 to under 12 yrs	15 mL every 4 hrs
children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- **each 15 mL contains:** sodium 7 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

butylated hydroxyanisole, edetate disodium, FD&C yellow no. 6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum

Questions?

1-800-719-9260

Principal Display Panel

LEADER™

Non-Drowsy

Daytime Cold & Flu

Acetaminophen

Dextromethorphan HBr

Phenylephrine HCl

Pain Reliever / Fever Reducer

Cough Suppressant

Nasal Decongestant

Relief of:

Aches

Fever

Cough

Sore Throat

Nasal Congestion

Alcohol-Free

COMPARE TO VICKS[®] DAYQUIL[®] Cold & Flu

active ingredients

100% Money Back Guarantee

12 FL OZ (335 mL)

LEADER²

NDC 70000-0191-2

Non-Drowsy

Daytime Cold & Flu

Acetaminophen
Dextromethorphan HBr
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Pain Reliever / Fever Reducer
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Relief of:
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Alcohol-Free

COMPARE TO
VICKS[®] DAYQUIL[®]
COLD & FLU
active ingredients*

100% Money
Back Guarantee

12 FL OZ (355 mL)

: 65640 E9 F4

DO NOT USE IF PRINTED
NECKBAND IS BROKEN
OR MISSING

DIST. BY CAH DUBLIN OH, 43017
www.myleader.com 1-800-200-6313

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100% Money Back Guarantee

CIN 5297957

Return to place of purchase if not satisfied.

REV. 5/22

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

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PEEL BACK AT
CORNER FOR MORE
INFORMATION

: 65640 E9 B1

Drug Facts (continued)

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ADHESIVE AREA
• NO VARNISH • NO TYPE

Drug Facts (continued)

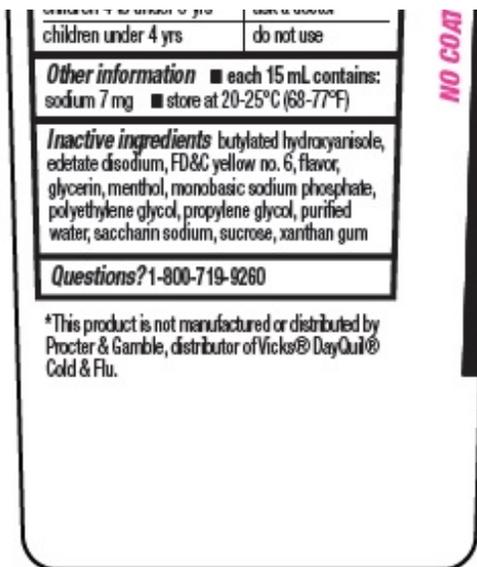
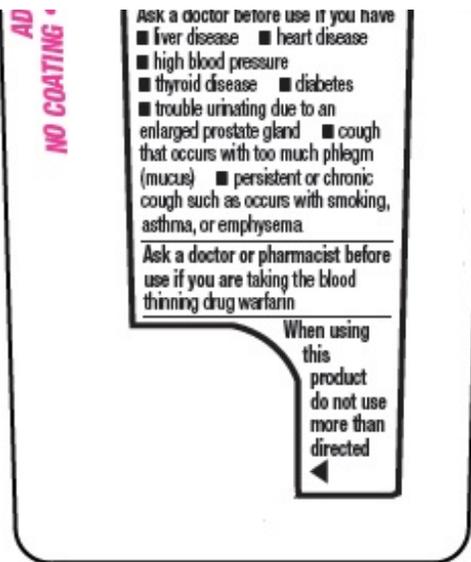
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LEADER DAYTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, phenylephrine hcl solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0191
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
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	ORANGE (clear)	Score	
Shape		Size	
Flavor	MENTHOL (with fruit)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0191-1	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/14/2016	
2	NDC:70000-0191-2	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/11/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	12/14/2016	

Labeler - Cardinal Health 110, LLC. dba Leader (063997360)

Revised: 9/2024

Cardinal Health 110, LLC. dba Leader