

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

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.

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
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 (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

Return to place of purchase if not satisfied.

CIN 5297957

REV. 5/22

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

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If a skin reaction occurs, stop use and seek medical help right away.

**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)

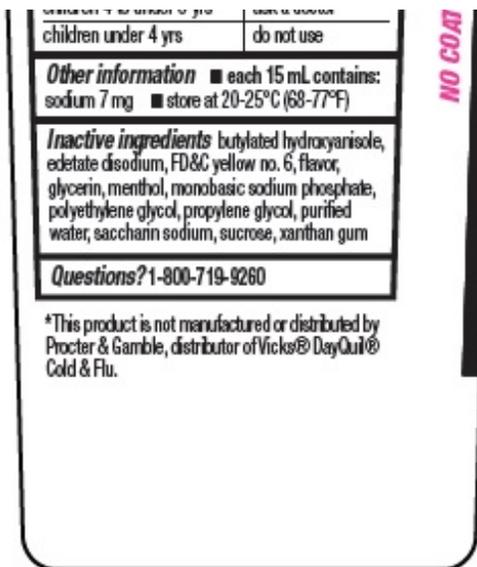
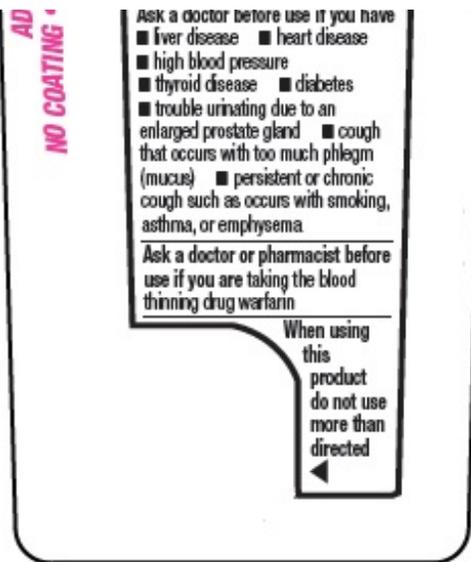
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LEADER DAYTIME COLD AND FLU

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 final	part341	12/14/2016	

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

Revised: 5/2023

Cardinal Health 110, LLC. dba Leader