

DAYTIME COLD AND FLU LIL DRUG STORE PRODUCTS- acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride liquid
Lil' Drug Store Products, Inc

Lil' Drug Store ® Daytime Cold & Flu

Drug Facts

<i>Active ingredients (in each 15 mL)</i>	<i>Purposes</i>
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
- sore throat
- nasal congestion
- fever
- 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.

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.
- 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 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 toll free **1-877-507-6516 (M-F 8AM-4:30PM CST)**

PRINCIPAL DISPLAY PANEL - 237 mL Bottle Label

[Quality Guaranteed caduceus]

Compare to the Active Ingredients in Vicks[®] DayQuil[®]

Original

Cold & Flu

Daytime

Acetaminophen, Pain Reliever/Fever Reducer

Phenylephrine HCl, Nasal Decongestant

Dextromethorphan HBr, Cough Supressant

Relieves

• Aches • Sore Throat • Fever

• Nasal Congestion • Cough

8 FL OZ

(237 mL)

[Lil' Drug Store logo]

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

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- skin reddening • blisters • rash

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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

◀ **LIFT LABEL FOR CONTINUED DRUG FACTS**



Compare to the Active Ingredients in Vicks® DayQuil®*

Original

Cold & Flu Daytime

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

Relieves

- Aches • Sore Throat • Fever
- Nasal Congestion • Cough

8 FL OZ (237 mL)



Product manufactured for:
Lil' Drug Store Products, Inc.
9300 Earhart Lane SW
Cedar Rapids, IA 52404

*This product is not manufactured or distributed by The Procter & Gamble Company. Vicks® and DayQuil® are registered trademarks of The Procter & Gamble Company.

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

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<p>Drug Facts (continued)</p> <p>(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.</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> • 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) <p>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</p> <p>When using this product, do not exceed recommended dosage.</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> • 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. <p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.</p> <p>Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of</p>	<p>Drug Facts (continued)</p> <p>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.</p> <p>Directions</p> <ul style="list-style-type: none"> • 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 <table border="1" style="width: 100%; font-size: x-small;"> <tr> <td>adults and children 12 years and over</td> <td>30 mL every 4 hours</td> </tr> <tr> <td>children 6 to under 12 years</td> <td>15 mL every 4 hours</td> </tr> <tr> <td>children 4 to under 6 years</td> <td>ask a doctor</td> </tr> <tr> <td>children under 4 years</td> <td>do not use</td> </tr> </table> <ul style="list-style-type: none"> • when using other Daytime or Nighttime products, carefully read each label to ensure correct dosing <p>Other information</p> <ul style="list-style-type: none"> • each 15 mL contains: sodium 12 mg • store between 20-25°C (68-77°F). Do not refrigerate. <p>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</p> <p>Questions or comments? Call toll free 1-877-507-6516 (M-F 8AM-4:30PM CST)</p>	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
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-6931	
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	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
SUCROSE (UNII: C151H8M554)				
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
WATER (UNII: 059QF0KO0R)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66715-6931-4	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/15/2016	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	12/01/2014		

Labeler - Lil' Drug Store Products, Inc (093103646)

Revised: 12/2023

Lil' Drug Store Products, Inc