DAYTIME COLD AND FLU MULTI-SYMPTOM RELIEF- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule Aurohealth LLC

DAYTIME COLD AND FLU Multi-Symptom Relief

Drug Facts

Active ingredients (in each capsule)

Acetaminophen USP 325 mg Dextromethorphan HBr USP 10 mg Phenylephrine HCl USP 5 mg

Purpose

Pain reliever/fever reducer Cough suppressant Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- cough due to minor throat & bronchial irritation
- sore throat
- headache
- minor aches & pains
- fever

Warnings

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

- more than 4 doses 24 hrs, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

Sore throatwarning:If sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see 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
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough 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
- symptoms get worse or last 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 directed can cause serious health problems. 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 & for children even if you do not notice any signs or symptoms.

Directions

- take only as directed see Overdose warning
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	2 capsules with water every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

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

Other information

store at room temperature

Inactive ingredients

citric acid anhydrous, gelatin, glycerin, Neelicert FD & C Red No. 40, Neelicert FD & C Yellow No. 6 noncrystallizing sorbitol solution, polyethylene glycol, povidone, propylene glycol, purified water, shellac glaze, titanium dioxide

Questions or comments?

call **1-855-274-4122**

Distributed by:

AUROHEALTH LLC

2572 Brunswick Pike Lawrenceville, NJ 08648

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - (16 Capsules Bottle)

AUROHEALTH NDC 58602-768-15

Compare to the active ingredients in VICKS [®] DayQuil [®] Cold & Flu Multi-Symptom Relief LiquiCaps ^{®*}

Multi-Symptom Relief Non-Drowsy Daytime Relief Cold & Flu Acetaminophen, Dextromethorphan HBr and Phenylephrine HCI Capsules 325 mg/10 mg/5 mg

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

16 Capsules

Drug Facts

Active ingredients (in each capsule) Purpose Acetaminophen USP 325 mg..... Dextromethorphan HBr USP 10 mg......Cough suppressant Phenylephrine HCI USP 5 mg......Nasal decongestant

Uses temporarily relieves common cold/flu symptoms: ■ nasal congestion ■ cough due to minor throat & bronchial imitation ■ sore throat ■ headache ■ minor aches & pains

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 4 doses in 24 hrs, which is the maximum daily amount for this product mwith other drugs containing acetaminophen = 3 or more alcoholic drinks

daily while using this product Sore throat warning: if sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see a doctor promptly.

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Drug Facts (continued)

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When using this product, do not use more than directed.

Stop use and ask a doctor if = you get nervous, dizzy or skepless = symptoms get worse or last 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.

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Drug Facts (continued)

Other information store at room temperature

Inactive ingredients

citric acid anhydrous, gelatin, glycerin, Neelicert FD & C Red No. 40, Neelicert FD & C Yellow No. 6, noncrystallizing

Drug Facts (continued)

sorbitol solution, polyethylene glycol, povidone, propylene glycol, purified water, shellac glaze, titanium dioxide

Questions or comments? call 1-855-274-4122

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Distributed by: **AUROHE AL TH LLC** 2572 Brunswick Pike Lawrenceville, NJ 08648



NDC 58602-768-15

Compare to the active ingredients in VICKS® DayQuil® Cold & Flu Multi-Symptom Relief LiquiCaps®*

Daytime Relief Cold & Flu

Multi-Symptom Relief Non-Drowsv

Acetaminophen, Dextromethorphan HBr and Phenylephrine HCl Capsules 325 mg/10 mg/5 mg

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

Capsules Actual Size

Failure to fellow these warnings sould result in serious consequences.

KEEP OUTER CARTON FOR COMPLETE PRODUCT IN FORMATION

TAMPER EVIDENT

Do not use if package is opened or if blister unit is torn, broken, or shows any signs of Tampering.

This product is not manufactured or distributed by Procter & Gamble, distributor of VICKS DayQuil* Cold & Flu Multi-Symptom Relief

DAYTIME COLD AND FLU MULTI-SYMPTOM RELIEF

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule

Product	Inform	ation
Product	11110111	ıatıvı

Product Type HUMAN OTC DRUG Item Code (Source) NDC:58602-768

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients			
Ingredient Name	Strength		
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
SORBITOL (UNII: 506T60A25R)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SHELLAC (UNII: 46N107B710)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			

Product Characteristics			
Color	orange (Orange to Reddish Brown)	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	Q01
Contains			

Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-768- 15	16 in 1 BOTTLE; Type 0: Not a Combination Product	12/31/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/31/2019	

Labeler - Aurohealth LLC (078728447)

Establishment				
Name	Address	ID/FEI	Business Operations	
APL HEALTHCARE LIMITED		650844777	manufacture(58602-768)	

Revised: 3/2024 Aurohealth LLC