COLD AND FLU MULTI-SYMPTOM RELIEF/COLD AND FLU NIGHTTIME RELIEF-
acetaminophen, phenylephrine hydrochloride, dextromethorphan hydrobromide, and doxylamine succinate
Chain Drug Consortium, LLC

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.

Drug Facts - Day Time

Active ingredients (in each capsule)

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

Drug Facts - Night Time

Active ingredients (in each capsule)

Acetaminophen USP 325 mg
Dextromethorphan HBr USP 15 mg
Doxylamine succinate USP 6.25 mg

Purpose - Day Time

Pain reliever/fever reducer
Cough suppressant
Nasal decongestant

Purpose - Night Time

Pain reliever/fever reducer
Cough suppressant
Antihistamine

Uses - Day Time

temporarily relieves common cold/flu symptoms:

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

Uses - Night Time

temporarily relieves common cold/flu symptoms:

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

Warnings - Day Time

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
- with 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.

Warnings - Night Time

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
- with 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.

Do not use - Day Time
- 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.

Do not use - Night Time
- 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.
- to make a child sleep

Ask a doctor before use if you have - Day Time

- 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 before use if you have - Night Time
- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema
- trouble urinating due to enlarged prostate gland

Ask a doctor or pharmacist before use if you are - Day Time

taking the blood thinning drug warfarin

Ask a doctor or pharmacist before use if you are - Night Time
- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product,

do not use more than directed.

When using this product - Night Time
- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, & tranquilizers may increase drowsiness

Stop use and ask a doctor if - Day Time
- 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.

Stop use and ask a doctor if - Night Time
- pain or cough gets worse or lasts more than 7 days
- 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.

If pregnant or breast-feeding, - Night Time

ask a health professional before use.

Keep out of reach of children. - Day Time

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.

Keep out of reach of children. - Night Time

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 - Day Time
- take only as directed – see Overdose warning
- do not exceed 4 doses per 24 hours

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

Directions - Night Time
- take only as directed – see Overdose warning
- do not exceed 4 doses per 24 hours

adults & children 12 yrs & over	2 capsules with water every 6 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 - Day Time

- store at room temperature

Other information - Night Time

- store at room temperature

Inactive ingredients - Day Time

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

Inactive ingredients - Night Time

D&C Yellow No. 10, gelatin, glycerin, Neelicert FD&C Blue No. 1, polyethylene glycol, povidone, propylene glycol, purified water, shellac glaze, sorbitol sorbitan solution, titanium dioxide

Questions or comments?

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

Distributed by:
Pharmacy Value Alliance, LLC

407 East Lancaster Avenue,

Wayne, Pa 19087

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 16 FL OZ (474 mL Bottle)

NDC 68016-879-18

Premier Value®

COMPARE TO THE ACTIVE INGREDIENTS IN VICKS® DAYQUIL® AND VICKS® Nyquil® COLD & FLU MULTI-SYMPTOM RELIEF LIQUICAPS®

Non-Drowsy Daytime | **Multi-Symptom Nighttime**

COLD & FLU RELIEF

Acetaminophen, | **Acetaminophen,**

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

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

32 Capsules

Dextromethorphan HBr, Doxylamine Succinate Capsules 325 mg/15 mg/6.25 mg

- Aches, Fever & Sore Throat
- Sneezing, Runny Nose
- Cough

16 Capsules

FBG907P

NDC 68016-879-48

Premier Value®

*COMPARE TO THE ACTIVE INGREDIENTS IN VICKS® DAYQUIL® AND VICKS® NyQuil® COLD & FLU MULTI-SYMPTOM RELIEF LIQUICAPS®

Non-Drowsy

Daytime

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

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

32 Capsules

Multi-Symptom

Nighttime

Acetaminophen, Dextromethorphan HBr, Doxylamine Succinate Capsules 325 mg/15 mg/6.25 mg

- Aches, Fever & Sore Throat
- Sneezing, Runny Nose
- Cough

16 Capsules

COLD & FLU RELIEF

48 Total Capsules

Drug Facts — Daytime Cold & Flu Relief

Active Ingredients (in each capsule) — **Purpose**

Acetaminophen USP 325 mg ..... Pain reliever/fever reducer
Dextromethorphan HBr USP 10 mg ..... Cough suppressant
Phenylephrine HCl USP 5 mg ..... 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 in 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 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.

Drug Facts — Nighttime Cold & Flu Relief

Active ingredients (in each capsule) — **Purpose**

Acetaminophen USP 325 mg ..... Pain reliever/fever reducer
Dextromethorphan HBr USP 15 mg ..... Cough suppressant
Doxylamine succinate USP 6.25 mg ..... Antihistamine

Uses temporarily relieves common cold/flu symptoms: ■ cough due to minor throat & bronchial irritation ■ sore throat ■ headache ■ minor aches & pains ■ fever ■ runny nose & sneezing

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 ■ with 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.

Drug Facts (continued) — Daytime Cold & Flu Relief

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

Drug Facts (continued) — Nighttime Cold & Flu Relief

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. ■ to make a child sleep

Ask a doctor before use if you have ■ liver disease ■ glaucoma ■ cough that occurs with too much phlegm (mucus) ■ a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema ■ trouble urinating due to enlarged prostate gland

Ask a doctor or pharmacist before use if you are ■ taking sedatives or tranquilizers ■ taking the blood thinning drug warfarin

When using this product ■ **do not use more than directed** ■ excitability may occur, especially in children ■ marked drowsiness may occur ■ avoid alcoholic drinks ■ be careful when driving a motor vehicle or operating machinery ■ alcohol, sedatives, & tranquilizers may increase drowsiness

Stop use and ask a doctor if ■ pain or cough gets worse or lasts more than 7 days ■ 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.

Drug Facts (continued) — Daytime Cold & Flu Relief

■ 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**

Drug Facts (continued) — Nighttime Cold & Flu Relief

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 6 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 D&C Yellow No. 10, gelatin, glycerin, Neelicert FD&C Blue No. 1, polyethylene glycol, povidone, propylene glycol, purified water, shellac glaze, sorbitol sorbitan solution, titanium dioxide

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

Lot:
EXP:

8 40986 03609 5

Distributed By:
Pharmacy Value Alliance, LLC
407 East Lancaster Avenue,
Wayne, Pa 19087

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

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

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® NyQuil® Cold & Flu Nighttime Relief LiquiCaps®.

Failure to follow these warnings could result in serious consequences.

KEEP OUTER CARTON FOR COMPLETE PRODUCT INFORMATION

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

COLD AND FLU MULTI-SYMPTOM RELIEF/COLD AND FLU NIGHTTIME RELIEF

acetaminophen, phenylephrine hydrochloride, dextromethorphan hydrobromide, and doxylamine succinate kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-879

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68016-879-48	1 in 1 PACKAGE; Type 0: Not a Combination Product	07/12/2019	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	16 BLISTER PACK	32
Part 2	8 BLISTER PACK	16

Part 1 of 2

DAYTIME COLD AND FLU MULTI-SYMPTOM RELIEF

acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride capsule

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	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**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
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: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	ORANGE (orange to reddish orange)	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	Q01
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		16 in 1 CARTON		
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/12/2019	

Part 2 of 2

NIGHTTIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate capsule

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	

GLYCERIN (UNII: PDC6A3C0OX)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	GREEN	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	Q07
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 in 1 CARTON		
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/12/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/12/2019	

Labeler - Chain Drug Consortium, LLC (101668460)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	MANUFACTURE(68016-879)

Revised: 12/2020 Chain Drug Consortium, LLC