DAYTIME COLD/FLU RELIEF SOFTGELS- acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled
Pharmacy Value Alliance, 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.

Daytime Cold/Flu Relief Softgels

DRUG FACTS

Active ingredients (in each softgel)
Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg

Purpose
Acetaminophen ……..…Pain reliever/fever reducer
Dextromethorphan HBr .....Cough suppressant
Phenylephrine HCI .....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 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, lasts more than 2 days, occurs with or is 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 • thyroid disease • diabetes • high blood pressure
• trouble urinating due to an enlarged prostate gland
• cough that occurs with too much phlegm (mucus)
• persistent or chronic 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 productdo 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.
In case of accidental overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as children, even if you do not notice any signs or symptoms.

Directions

• take only as recommended (see Warnings)
• do not exceed 4 doses per 24 hours

adults & children 12 years & over	2 softgel with water every 4 hours
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 20-25ºC (68-77ºF)
• avoid excessive heat

Inactive ingredients FD&C Red #40, FD&C Yellow #6, gelatin, Glycerin, Polyethylene glycol, Povidone, Propylene glycol, Purified water, Sorbitol sorbitan solution Titanium dioxide

Questions? Call weekdays from 9:30 am to 4:30 pm EST.
1-877-798-5944

Principal Display Package

Premier
Value®

***COMPARE TO THE ACTIVE INGREDIENTS IN VICKS® DAYQUIL® LIQUICAPS®**

Non-Drowsy

Daytime

COLD/FLU RELIEF

***Acetaminophen** / Dextromethorphan HBr / Phenylephrine HCl*

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

Alcohol - Free

Antihistamine - Free

16 Softgels

**This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® DayQuil® LiquiCaps®.

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

INDEPENDENTLY TESTED
PV
SATISFACTION GUARANTEED

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

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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Premier Value®

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Actual Size

Non-Drowsy **Daytime** COLD/FLU RELIEF

Premier Value®

Drug Facts

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Drug Facts (continued)

■ minor aches & pains ■ fever

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Drug Facts (continued)

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DAYTIME COLD/FLU RELIEF SOFTGELS

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-880
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
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange (to red)	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	604
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-880-16	2 in 1 PACKAGE	02/28/2020	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:68016-880-24	2 in 1 PACKAGE	02/28/2020	
2		12 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	02/28/2020	

Labeler - Pharmacy Value Alliance, LLC (101668460)

Registrant - AptaPharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(68016-880) , repack(68016-880)