GENCARE DAYTIME COLD AND FLU SOFTGEL- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

Pioneer Life Sciences, LLC

Gencare DayTime Cold and Flu Softgel (Acetaminophen 325mg, Dextromethorphan HBr 10mg, Phenylephrine HCl 5mg)

Drug Facts

Active ingredients (in each softgel)

Acetaminophen 325mg

Dextromethorphan HBr 10mg

Phenylephrine HCl 5mg

Purpose

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

Warning

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, 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
- 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
- pain, nasal congestion or cough get worse or last 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: In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults & for children even if you do not notice any signs or symptoms.

Directions

- take only as directed
- do not exceed 4 doses per 24 hrs.

Adults and children 12 yrs and over	take 2 softgels with water every 4 hrs.
Children 4 to under 12 yrs	ask a doctor
Children under 4 yrs	do not use

Other information

■ store at room temperature

Inactive ingredients

Polyethylene Glycol400, Propylene Glycol, Povidone, Gelatin, Sorbitol Sorbitan Anhydrous, Glycerin, Allura Red, FD & C Yellow 6/Sunset Yellow, Titanium Dioxide.

Questions or Comments?

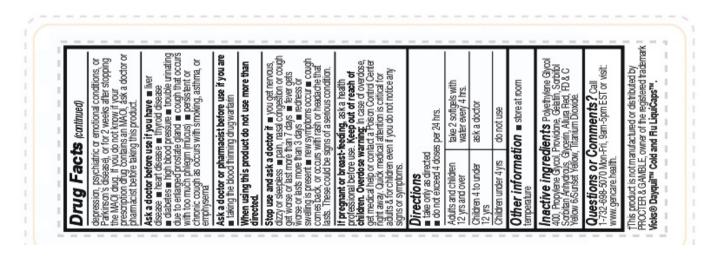
Call 1-732-698-5070 Mon-Fri, 9am-5pm EST or visit: www.gencare.health.

This product is not manufactured or distributed by PROCTER & GAMBLE, owner of the registered trademark Vicks® Dayquil™ Cold and Flu LiquiCaps™.

Distributed by: Gencare Consumer Products, LLC 40E Cotters Ln, Suite A, East Brunswick, NJ 08816

NDC 72090-005-01- 48 Softgels





GENCARE DAYTIME COLD AND FLU SOFTGEL

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72090-005
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: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients	
Ingredient Name	Strength

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE (UNII: FZ989GH94E)	
Gelatin (UNII: 2G86QN327L)	
Sorbitol (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	red	Score	no score
Shape	capsule	Size	19mm
Flavor		Imprint Code	A09
Contains			

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:72090-005- 01	48 in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/08/2023	

Labeler - Pioneer Life Sciences, LLC (014092742)

Revised: 11/2024 Pioneer Life Sciences, LLC