DAYTIME COLD AND FLU MULTI SYMPTOM RELIEF- acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled Shield Pharmaceuticals Corp

Daytime Cold and Flu Multi-Symptom Relief Drug Facts

Active ingredient (in each softgel)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 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 8 Softgels 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

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 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
- high blood pressure
- thyroid disease
- diabetes
- 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 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.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. 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 & for children even if you do not notice any signs or symptoms.

Directions

take only as directed do not exceed 8 softgels per 24 hrs

adults & children 12 yrs & over	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 between 20-25°C (68-77°F).

Avoid high humidity and excessive heat. Protect from light.

Questions or comments?

1-800-373-6981 (toll-free)

Inactive ingredients

butylated hydroxyanisole, FD&C Yellow No. 6, gelatin, glycerin, methylparaben, polyethylene glycol-400, propylene glycol, propylparaben, povidone, purified water, sorbitol

Distributed by:

Shield Pharmaceuticals Corp.

Hauppauge, NY 11788

PRINCIPAL DISPLAY PANEL

ValuRx

Compare to the Active Ingredients in Alka-Seltzer Plus® Cold & Flu Maximum Strengths

Daytime Cold & Flu

Multi-Symptom Relief

Acetaminophen
Dextromethorphan HBr
Phenylephrine HCl

- Headache, Fever, Sore Throat,
- Minor Aches & Pain
- Nasal Congestion,
- Sinus Pressure
- Cough

Carton



DAYTIME COLD AND FLU MULTI SYMPTOM RELIEF

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:83059-0030 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	5 mg	

Inactive Ingredients			
Ingredient Name	Strength		
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GELATIN (UNII: 2G86QN327L)			

GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
POVIDONE (UNII: FZ989GH94E)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	orange	Score	no score
Shape	CAPSULE	Size	21mm
Flavor		Imprint Code	SD25
Contains			

F	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:83059- 0030-1	1 in 1 CARTON	04/07/2024		
1	_	10 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 Drug	M012	04/07/2024	

Labeler - Shield Pharmaceuticals Corp (118724924)

Revised: 9/2024 Shield Pharmaceuticals Corp