

FACOL CLASSIC ONE- acetaminophen, guaifenesin, pseudoephedrine hydrochloride, dl-methylephedrine hydrochloride, cloperastine hydrochloride, chlorpheniramine maleate capsule
OASIS TRADING

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Acetaminophen, Guaifenesin, Pseudoephedrine Hydrochloride, DL-Methylephedrine Hydrochloride, Cloperastine Hydrochloride, Chlorpheniramine Maleate

relieve your cold symptoms

Keep out of reach of children

- adult and children 12 years of age and older: 2 capsules every 5 hours
- children under 12 years of age: ask a doctor

Warnings

When using this product

Do not use for a period longer than 1 weeks

Stop use and ask a doctor if nervousness, dizziness, or sleepiness occur. Pain, nasal congestion or cough gets worse or lasts more than 7 days.

fever gets worse or lasts more than 3 days

New symptoms occur

These may 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 overdose, get medical help or contact a poison control center right away

camauba wax cellulose, starch

For oral use only

FACOL CLASSIC ONE

<i>Drug Facts</i>	
Active Ingredients (in one capsule)	Purpose
Acetaminophen 200mg	Aches and pain
Chlorpheniramine Maleate 1.25mg	Antihistamine
Cloperastine Hydrochloride 8mg	Fever
DL-Methylephedrine Hydrochloride 12.5mg	Dry cough
Guaifenesin 41.6mg	Runny Nose & Sneezing (Nighttime only)
Pseudoephedrine Hydrochloride 15mg	Nasal congestion
Uses	
■ relieve your cold symptoms	
Warnings	
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fever gets worse or lasts more than 3 days	
New symptoms occur	
These may 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 overdose, get medical help or contact a poison control center right away	
Directions	
■ adult and children 12 years of age and older: 2 capsules every 5 hours	
■ children under 12 years of age: ask a doctor	
Other Information	
■ Store at room temperature	
Inactive Ingredient	
camauba wax cellulose, starch	
Questions or comments ?	
Call weekdays from 9 a.m to 5 p.m EST at (201) 669-8405	
Distributed By: P&K FRONTIER MARKETING CORP.	
329 BROAD AVENUE # 2F, PALISADES PARK, NJ 07650, USA	
Made in South Korea	

FACOL CLASSIC ONE

acetaminophen, guaifenesin, pseudoephedrine hydrochloride, dl-methylephedrine hydrochloride, cloperastine hydrochloride, chlorpheniramine maleate capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72689-0013	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	200 mg	
	GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	41.6 mg	
	PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	15 mg	
	METHYLEPHEDRINE HYDROCHLORIDE, (+/-)- (UNII: 99214P83XM) (METHYLEPHEDRINE, (+/-)- - UNII:SHS9PGQ2LS)	METHYLEPHEDRINE HYDROCHLORIDE, (+/-)-	12.5 mg	
	CLOPERASTINE HYDROCHLORIDE (UNII: PI4N7C63ND) (CLOPERASTINE - UNII:69M5L7BXEK)	CLOPERASTINE HYDROCHLORIDE	8 mg	
	CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	1.25 mg	
Inactive Ingredients				
	Ingredient Name	Strength		
	STARCH, CORN (UNII: O8232NY3SJ)			
Product Characteristics				
Color	brown	Score	no score	
Shape	OVAL	Size	22mm	
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72689-0013-1	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	11/22/2018	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		11/22/2018		

Labeler - OASIS TRADING (689991468)

Registrant - OASIS TRADING (689991468)

Establishment

Name	Address	ID/FEI	Business Operations
OASIS TRADING		689991468	manufacture(72689-0013) , label(72689-0013)

