

**FACOL COLD AND FLU NIGHT- acetaminophen, guaifenesin, phenylephrine hcl, dextromethorphan hbr, diphenhydramine hcl capsule, liquid filled
JW HOLDINGS**

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.

FACOL COLD AND FLU NIGHT

Active Ingredients (in each tablet) Purpose

Acetaminophen 200mgpain
reliever /fever reducer
Guaifenesin 35mg.....
.....expectorant
Phenylephrine HCl 5mg.....nasal
decongestant
Dextromethorphan HBr 8mg.....cough suppression
Diphenhydramine HCl 15mg.....antihistamine

Inactive Ingredients

purified water, polyethylene glycol 400, propylene glycol, gelatin, povidone, sorbitol, gardenia blue

Uses

■ temporary relief of the following cold symptoms. ■ sore throat ■ minor aches and pains ■ headache ■ fever ■ nasal congestion ■ sinus congestion and pressure ■ cough

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 10 caplets in 24 hours. Severe liver damage may occur if you take
■ more than 4,000 mg of acetaminophen in 24 hours
■ with other drugs containing acetaminophen
■ 3 or more alcoholic drinks every day while using this product

INDICATIONS & USAGE

Relief cold symptoms and minor pains.

Directions

- adults and children 15 years and older: take 2 capsules after a meal 2 times a day ■
Do not take more than directed
- children under 15 years: do not use and ask a doctor.

Ask a doctor before use if

you have ■ allergic reaction ■ asthma ■ liver disease ■ pregnant or breast feeding ■
medical care ■ glaucoma ■ high blood pressure ■ thyroid disease ■ heart disease ■
diabetes

Ask a doctor or pharmacist before use if you

- taking sedatives or tranquilizers ■ having chicken pox or other infections
- taking the blood thinning drug warfarin

Do not use

- For children who are younger than 3 months old. (new born baby)
- If you ever had an allergic reaction to this product or any of its ingredients.
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or a 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 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or a pharmacist)

Keep out of reach of children.

If pregnant or breast-feeding

Do not take this drug and ask a health professional

Questions or Comments?

1-562-695-2818 Monday - Friday 9AM-5PM WET

Distributed by: Bio Mission Group Inc.

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness, constipation occurs
- redness or swelling is present ■ fever get worse or lasts more than 3 days
- new severe symptoms occur such as shock (anaphylaxis), Stevens Johnson Syndrome, Lyell Syndrome, Asthma, Dyshepatia or Interstitial lung diseases.
- pain, cough, nasal congestion gets worse or lasts after 5-6 times of taking a dose.

When using this product

- Do not exceed recommended dose. Do not drink when taking doses
- Avoid drive or use of machineries.

Other Information

- Store between room temperature 20-25°C (68-77°F)
- Avoid direct light or humid condition and excessive heat

Overdose warning

Do not exceed recommended dose. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-333-2333).

NDC 69365-003-01

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Facol Cold & Flu Night

MULTI

Soft liquid-filled capsule

Guaifenesin-Expectorant

Acetaminophen-Fever/pain reliever

Phenylephrine HCl-Nasal Decongestant


Dextromethorphan HBr- Cough Suppressant

Diphenhydramine HCl-Antihistamine

sleep aid

10 capsules

JW Pharmaceuticals

장(mm)	폭(mm)	고(mm)	원료약품(pt)	본문(pt)	사용기한(pt)	컬러
120	75	15	7	7	7	

Drug Facts Active Ingredients (in each softgel) Acetaminophen 200mg.....pain reliever /fever reducer Guaifenesin 35mg.....expectorant ▶	Purpose nasal decongestant cough suppressant antihistamine	Drug Facts (continued) Phenylephrine HCl 5mg.....nasal decongestant Dextromethorphan HBr 8mg.....cough suppressant Diphenhydramine 18.75mg.....antihistamine
Drug Facts (continued) Use for temporary relief of the cold symptoms - sore throat	Drug Facts (continued) When using this product - do not exceed recommended dose	

of No. :
xp. Date :

uses ■ temporary relief of the cold symptoms ■ sore throat
■ minor aches and pains ■ headache ■ fever ■ nasal congestion
■ sinus congestion ■ cough

Warnings
Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 10 capsules in 24 hours. Severe liver damage may occur if you take ■ more than 4,000 mg of acetaminophen in 24 hours ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product

Do not use
■ in children under 12 years of age ■ If you ever had an allergic reaction to this product or any of its ingredients. ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or a pharmacist. ■ If you are now taking a prescription monoamine oxidase inhibitor (MAOI) or 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or a pharmacist ■ to make child sleep

Ask a doctor before use if you have
■ liver disease ■ asthma, chronic bronchitis or emphysema ■ thyroid disease ■ heart disease ■ diabetes ■ glaucoma ■ high blood pressure

Ask a doctor or pharmacist before use if you are
■ taking sedatives or tranquilizers ■ having chicken pox or other infections ■ taking the blood thinning drug warfarin

When using this product ■ do not exceed recommended use ■ do not drink when taking doses ■ be careful when driving motor vehicle ■ drowsiness may occur ■ avoid alcoholic drinks

Stop use and ask a doctor if
■ nervousness, dizziness, or sleeplessness, constipation occurs
■ redness or swelling is present
■ fever get worse or lasts more than 3 days ■ new severe symptoms occur
■ pain, cough, nasal congestion gets worse or lasts after 5-6 times of taking a dose.

If Pregnant or breast-feeding, do not take this drug and ask a health professional
Keep out of reach of children.
Overdose warning: do not exceed recommended dose. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-333-2333).

Directions
■ adults and children 15 years and older: take 2 capsule after a meal or before sleep ■ do not take more than directed
■ children under 15 years: do not use and ask a doctor

Other Information
■ Store between room temperature 20-25°C (68-77°F)
■ Avoid direct light or humid condition and excessive heat

Drug Facts (continued)
Inactive Ingredients purified water, polyethylene glycol 400, propylene glycol, gelatin, povidone, sorbitol, gardenia blue

Drug Facts (continued)
Questions or Comments? 1-562-695-2818 Monday-Friday 9AM-5PM WET Distributed by: Bio Mission Group Inc.

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정제된 액상 캡슐
-20°C 이하 보관

NDC: 69365-003-01 KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

초기 감기엔 확실하게 확!

화쿨® MULTI
FACOL®
COLD and FLU
soft liquid filled capsule

sleep aid
Night

10 capsules

iw pharmaceuticals

Guaifenesin-Expectorant
Acetaminophen-Fever/Pain reliever
Phenylephrine HCl-Nasal Decongestant
Dextromethorphan HBr-Cough suppressant
Diphenhydramine HCl-Antihistamine

FACOL COLD AND FLU NIGHT

acetaminophen, guaifenesin, phenylephrine hcl, dextromethorphan hbr, diphenhydramine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69365-003
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	200 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	35 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	8 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	18.75 mg

Inactive Ingredients

Ingredient Name	Strength
GARDENIAN BLUE (UNII: 54A6568109)	0.49 mg
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	440.25 mg
WATER (UNII: 059QF0KO0R)	70.4 mg
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	40 mg
POVIDONE K29/32 (UNII: 390RMW2PEQ)	33 mg
GELATIN (UNII: 2G86QN327L)	206.22 mg
SORBITOL (UNII: 506T60A25R)	142.88 mg

Product Characteristics

Color	blue (Light bluish liquid filled soft gel)	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	FacN
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69365-003-01	1 in 1 CARTON	08/01/2015	
1		1 in 1 BLISTER PACK		
1		10 in 1 CAPSULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/01/2015	

Labeler - JW HOLDINGS (631094492)

Registrant - JW HOLDINGS (631094492)

Establishment

Name	Address	ID/FEI	Business Operations
RP Bio Inc.		689851235	manufacture(69365-003) , pack(69365-003) , analysis(69365-003) , label(69365-003) , sterilize(69365-003)

Revised: 11/2022

JW HOLDINGS