

**FACOL COLD AND FLU DAY AND NIGHT- acetaminophen, guaifenesin, phenylephrine hcl, dextromethorphan hbr, diphenhydramine hcl, lac color, gardenia blue 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 DAY AND NIGHT

**Active Ingredients for DAY (In each capsule).....Purpose
Active Ingredients for NIGHT (In each capsule).....Purpose**

Acetaminophen 200mg.....pain reliever/fever reducer
Guaifenesin 35mg.....expectorant
phenylephrine HCl 5mg.....nasal decongestant
dextromethorphan Hbr8mg.....cough suppressant
Acetaminophen 200mg.....pain reliever/fever reducer
Guaifenesin 35mg.....expectorant
phenylephrine HCl 5mg.....nasal decongestant
dextromethorphan Hbr8mg.....cough suppressant
Diphenhydramine Hydrochloride 18.75mg.....antihistamine

Uses

■ temporary relief of the following 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 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

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

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 drink when taking doses ■ Do not exceed recommended dose
■ be careful when driving motor vehicle (nighttime capsule)

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).

Other Information

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

Inactive Ingredients

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

Questions or Comments?

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

Distributed by: Bio Mission Group Inc.

Directions

- Do not take more than directed
- children under 15 years: ask a doctor
- adults and children 15 years and over: take 2 daytime capsules 2 times a day
- Take 2 nighttime capsules before sleep
- do not take nighttime capsule and daytime capsule together

temporarily relieves common cold and flu symptoms and minor aches

NDC 69365-004-01

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION
DO NOT TAKE DAY CAPSULE AND NIGHT CAPSULE TOGETHER

Facol Cold & Flu Day & Night

MULTI

Soft liquid filled capsule

Guaifenesin-expectorant

Acetaminophen-Fever/pain reliever

Phenylephrine HCl-Nasal Decongestant

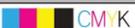
Dextromethorphan HBr- Cough Suppressant

Diphenhydramine HCl-antihistamine (night time capsule only)

non drowsy Day

sleep aid Night

10 capsulesJW Pharmaceuticals

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

Lot No. : Exp. Date :	Drug Facts Active Ingredients for DAY (in each capsule) Purpose Acetaminophen 200mg.....pain reliever /fever reducer Guaifenesin 35mg.....expectorant ▶	Drug Facts (continued) Phenylephrine HCl 5mg.....nasal decongestant Dextromethorphan HBr 8mg.....cough suppressant ▼	Drug Facts (continued) Questions or Comments? 1-800-443-7381 (toll-free) 9AM-5PM WET Distributed by JW Mission Group, Inc. 8 800-443-7381 140015	
	Drug Facts (continued) Active Ingredients for NIGHT (in each capsule) Purpose Acetaminophen 200mg.....pain reliever /fever reducer Guaifenesin 35mg.....expectorant Phenylephrine HCl 5mg.....nasal decongestant Dextromethorphan HBr 8mg.....cough suppressant Diphenhydramine HCl 18.75mg.....antihistamine	Drug Facts (continued) Ask a doctor or pharmacist before use if you are ■ taking sedatives or tranquilizers ■ having chicken fox or other infections ■ taking the blood thinning drug warfarin When using this product ■ do not drink when taking doses ■ do not exceed recommended dose ■ be careful when driving motor vehicle (nighttime capsule)		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).
	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 Ask a doctor before use if you have ■ liver disease ■ asthma, chronic bronchitis or emphysema ■ thyroid disease ■ heart disease ■ diabetes ■ glaucoma ■ high blood pressure ▶	Directions ■ Do not take more than directed ■ children under 15 years: ask a doctor ■ adults and children 15 years and over: take 2 daytime capsules 2 times a day ■ Take 2 nighttime capsule before sleep ■ do not take nighttime capsule and daytime capsule together ▼		
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 DO NOT TAKE DAY CAPSULE AND NIGHT CAPSULE TOGETHER

초기 감기엔 확실하게 확!

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

DAY&NIGHT

non drowsy
Day

sleep aid
Night

10 capsules

JW pharmaceuticals

Guaifenesin-Expectorant
 Acetaminophen-Fever/Pain reliever
 Phenylephrine HCl-Nasal Decongestant
 Dextromethorphan HBr-Cough suppressant
 Diphenhydramine HCl-antihistamine (night time capsule only)

FACOL COLD AND FLU DAY AND NIGHT

acetaminphen, guaifenesin, phenylephrine hcl, dextromethorphan hbr, diphenhydramine hcl, lac color, gardenia blue capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69365-004
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	18.75 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	8 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	35 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	206.22 mg
POVIDONE K29/32 (UNII: 390RMW2PEQ)	33 mg
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	40 mg
WATER (UNII: 059QF0KO0R)	70.4 mg
SORBITOL (UNII: 506T60A25R)	142.88 mg
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	440.25 mg
ALUMINUM OXIDE (UNII: LMI26O6933)	2.185 mg
COCHINEAL (UNII: TZ8Z31B35M)	2.185 mg
GARDENIAN BLUE (UNII: 54A6568109)	0.49

Product Characteristics

Color	yellow (soft liquid filled capsule) , blue (soft liquid filled capsule)	Score	no score
Shape	CAPSULE (rounded liquid filled cap)	Size	20mm
Flavor		Imprint Code	DFDN
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69365-004-01	1 in 1 CARTON	08/01/2015	
1		1 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 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(69365-004) , pack(69365-004) , label(69365-004) , sterilize(69365-004) , analysis(69365-004)

Revised: 11/2022

JW HOLDINGS