

FACOL COLD AND FLU DAY- acetaminophen, guaifenesin, phenylephrine hcl, dextromethorphan hydrobromide capsule, liquid filled
JW Holdings

FACOL COLD AND FLU DAY

Active Ingredient(in each tablet) Purpose

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

Inactive Ingredients

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

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 mild to moderately severe pain, Temporarily reduce multi cold symptom

Directions

- Do not take more than directed (see overdose warning)
- adults and children 15 years and older: take 2 capsules after a meal 2 times a day
- swallow whole-do not crush, chew or dissolve
- do not take night time capsule in less than 6 hours after taking day time capsule
- children under 15 years: do not use and ask a doctor.

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

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

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).

PRINCILA DISPLAY PANEL

NDC 69365-001-01

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Facol® Cold and Flu Day

MULTI

Soft liquid-filled capsule

Guaifenesin-Expectorant


Acetaminophen-Fever/Pain Reducer


Phenylephrine HCl-Nasal Decongestant

Dextromethorphan HBr-Cough Suppressant

10 capsules

JW pharmaceuticals

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

Lot No. : Exp. Date :	Drug Facts Active Ingredients (in each capsule) 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) 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 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 ▶	Drug Facts (continued) When using this product ■ do not exceed recommended dose ■ do not drink when taking doses 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 ■ do not take more than directed (see overdose warning) ■ adults and children 15 years and older: take 2 capsules after a meal 2 times a day ■ do not take night time capsule in less than 6 hours after taking day time capsule ■ 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, lac color	Drug Facts (continued) Questions or Comments? 1-562-695-2818 Monday-Friday 9AM-5PM WET Distributed by: Bio Mission Group Inc.	
	NDC: 69365-001-01 KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION		

초기 감기엔 확실하게 확!

화쿨[®] MULTI FACOL[®]

DAY COLD and FLU soft liquid filled capsule

non drowsy
Day

10 capsules

iw pharmaceuticals

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

FACOL COLD AND FLU DAY

acetaminophen, guaifenesin, phenylephrine hcl, dextromethorphan hydrobromide capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69365-001
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	35 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	8 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	40 mg
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	459 mg
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	40 mg
GELATIN (UNII: 2G86QN327L)	203.93 mg
POVIDONE K29/32 (UNII: 390RMW2PEQ)	33 mg
SORBITOL (UNII: 506T60A25R)	141.1 mg
COCHINEAL (UNII: TZ8Z31B35M)	2.185 mg
ALUMINUM OXIDE (UNII: LMI26O6933)	2.185 mg

Product Characteristics

Color	yellow	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	FacD
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69365-001-01	1 in 1 KIT	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 Drug	M012	08/01/2015	

Labeler - JW Holdings (631094492)

Registrant - JW Holdings (631094492)

Establishment

Name	Address	ID/FEI	Business Operations
RP Bio Inc.		689851235	manufacture(69365-001) , pack(69365-001) , analysis(69365-001) , label(69365-001) , sterilize(69365-001)

Revised: 8/2024

JW Holdings