

**FACOL COLD AND FLU DAY- acetaminophen, guaifenesin, phenylephrine hcl, dextromethorphan hydrobromide 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.*

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**FACOL COLD AND FLU DAY**

**Active Ingredient(in each tablet) Purpose**

Acetaminophen 200mg .....pain 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



상(mm)	폭(mm)	고(mm)	현료약중(pt)	본문(pt)	사용기안(pt)	컬러
120	75	15	7	7	7	 CMYK

Lot No. : Exp. Date :	<b>Drug Facts</b> <b>Active Ingredients (in each capsule)</b> Acetaminophen 200mg.....pain reliever /fever reducer Guaifenesin 35mg.....expectorant ▶	<b>Purpose</b> Phenylephrine HCl 5mg.....nasal decongestant Dextromethorphan HBr 8mg.....cough suppressant ▼
	<b>Drug Facts (continued)</b> <b>Uses</b> ■ temporary relief of the cold symptoms. ■ sore throat ■ minor aches and pains ■ headache ■ fever ■ nasal congestion ■ sinus congestion ■ cough <b>Warnings</b> <b>Liver warning:</b> 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 <b>Do not use</b> ■ 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 <b>Ask a doctor before use if you have</b> ■ liver disease ■ asthma, chronic bronchitis or emphysema ■ thyroid disease ■ heart disease ■ diabetes ■ glaucoma ■ high blood pressure <b>Ask a doctor or pharmacist before use if you are</b> ■ taking sedatives or tranquilizers ■ having chicken fox or other infections ■ taking the blood thinning drug warfarin ▶	<b>Drug Facts (continued)</b> <b>When using this product</b> ■ do not exceed recommended dose ■ do not drink when taking doses <b>Stop use and ask a doctor if</b> ■ 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. <b>If Pregnant or breast-feeding,</b> do not take this drug and ask a health professional <b>Keep out of reach of children.</b> <b>Overdose warning:</b> do not exceed recommended dose. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-333-2333). <b>Directions</b> ■ 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. <b>Other Information</b> ■ Store between room temperature 20-25°C (68-77°F) ■ Avoid direct light or humid condition and excessive heat ▼
	<b>Drug Facts (continued)</b> <b>Inactive Ingredients</b> purified water, polyethylene glycol 400, propylene glycol, gelatin, povidone, sorbitol, lac color	<b>Drug Facts (continued)</b> <b>Questions or Comments?</b> 1-562-695-2818 Monday-Friday 9AM-5PM WET Distributed by: Bio Mission Group Inc.
	8 806449 140114 	#정품인증 2016.07.14

NDC: 69365-001-01      KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

초기 감기엔 확실하게 확!

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

non drowsy  
 Day

10 capsules

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

**iw** pharmaceuticals

## FACOL COLD AND FLU DAY

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

filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69365-001
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

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

**Product Characteristics**

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	FacD
<b>Contains</b>			

**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 not			

OTC monograph not final	part343	08/01/2015	
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**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: 11/2022

JW Holdings