ACETAMINOPHEN DEXTROMETHORPHAN HYDROBROMIDE AND PHENYLEPHRINE HYDROCHLORIDE- acetaminophen, phenylephrine hydrochloride, and dextromethorphan hydrobromide capsule, liquid filled
J.P. BUSINESS ENTERPRISE

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.

ACETAMINOPHEN DEXTROMETHORPHAN HBr & PHENYLEPHRINE HCL SOFTGEL CAPSULES

Drug Facts

Active ingredients (in each softgel)	***Purpose***
Acetaminophen 325 mg, USP	Pain reliever/fever reducer
Dextromethorphan Hydrobromide 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:
- minor aches
- pains
- sore throat
- fever
- muscular aches
- headaches
- nasal congestion
- cough

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take:
- more than 4 doses in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Sore throat warning

If sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see a doctor promptly.

Do not use
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or 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 for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a

doctor or pharmacist before taking this product.

Ask a doctor before use if you have
- liver disease
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are taking the blood-thinning drug Warfarin.

When using this product
- **do not use more than directed.**

Stop use and ask a doctor if
- you get nervous, dizzy, or sleepless
- symptoms get worse or last more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back, or occurs with rash or headache that lasts

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning

Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults and for children, even if you do not notice any signs or symptoms.

Directions
- Take only as directed—see **Overdose warning.**
- do not exceed 4 doses per 24 hours.

adults and children 12 years of age and over	swallow 2 softgels with water
children 4 to under 12 years of age	ask a doctor
children under 4 years of age	**do not use**

If taking Daytime and Nighttime softgels carefully read each label to insure correct dosing

Other information
- store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat
- this product does not contain phenylpropanolamine

Inactive ingredients

FD&C Yellow No. 6, FD&C Red No. 40, gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide

Questions or comments?

1-888-333-9792

Distributed By: J.P Business Enterprise
Lake Grove, NY 11755

PRINCIPAL DISPLAY PANEL - 10 Capsule Blister Pack Carton

VALUMEDS

SEE NEW WARNINGS INFORMATION

Compare to the active ingredients
in **VICKS® DAYQUIL®***

NON-DROWSY
DAY TIME

COLD & FLU MULTI-SYMPTOM RELIEF

ACETAMINOPHEN, DEXTROMETHORPHAN HBr, PHENYLEPHERNE HCl

- Pain Reliever
- Fever Reducer
- Cough Suppressant
- Nasal Decongestant

10 SOFTGELS
Liquid filled capsules

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Uses temporarily relieves common cold/flu symptoms:

- minor aches
- pains
- sore throat
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- headaches
- nasal congestion
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▶

Drug Facts (continued)

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Stop use and ask a doctor if ■ you get nervous, dizzy, or sleepless ■ symptoms get worse or last more than 7 days ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ new symptoms occur ■ cough comes back, or occurs with rash or headache that lasts

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VALUMEDS

NON-DROWSY
DAY TIME

40001

VALUMEDS

SEE NEW WARNINGS INFORMATION

Compare to the active ingredients in **VICKS® DAYQUIL®***

NON-DROWSY
DAY TIME

COLD & FLU MULTI-SYMPTOM RELIEF

ACETAMINOPHEN, DEXTROMETHORPHAN HBr, PHENYLEPHERNE HCl

- Pain Reliever

*This product is not manufactured or distributed by Proctor & Gamble owner of the registered trademark Vicks® DayQuil®

PACKAGE IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE.
USE ONLY IF BLISTERS ARE INTACT.

ACETAMINOPHEN DEXTROMETHORPHAN HYDROBROMIDE AND PHENYLEPHRINE HYDROCHLORIDE

acetaminophen, phenylephrine hydrochloride, and dextromethorphan hydrobromide capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59105-004
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE K30 (UNII: U725QWY32X)	
WATER (UNII: 059QF0KO0R)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	red	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	512
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59105-004-10	1 in 1 CARTON	12/01/2014	
1		10 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	12/01/2014	

Labeler - J.P. BUSINESS ENTERPRISE (078775890)

Establishment

Name	Address	ID/FEI	Business Operations
MEDGEL PVT LTD		677385498	manufacture(59105-004)

Revised: 12/2019 J.P. BUSINESS ENTERPRISE