

ACETAMINOPHEN DEXTROMETHORPHAN HYDROBROMIDE AND DOXYLAMINE SUCCINATE- acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate 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 & DOXYLAMINE SUCCINATE SOFTGEL CAPSULES

Drug Facts

<i>Active ingredients (in each softgel)</i>	<i>Purpose</i>
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan Hydrobromide 15 mg	Cough suppressant
Doxylamine Succinate 6.25 mg	Antihistamine

Uses

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches/pains
- fever
- runny nose and sneezing

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, or 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.
- to make a child sleep

Ask a doctor before use if you have

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood-thinning drug warfarin.

When using this product

- **do not use more than directed**
- excitability may occur especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful with driving a motor vehicle or operating machinery
- alcohol, sedatives and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- pain or cough gets worse or lasts 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.
These could be signs of a serious condition

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

Keep out of reach of children.

Overdose warning

Taking more than the recommended dose 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 as well as for children, even if you do not notice any signs or symptoms.

Directions

- Take only as recommended—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 every 6 hours
children 4 to under 12 years of age	ask a doctor
children under 4 years of age	do not use

If taking Nighttime and Daytime 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

D&C Yellow No. 10, FD&C Blue No. 1, 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 Softgel Blister Pack Carton

VALUMEDS

SEE NEW WARNINGS INFORMATION

Compare to the active ingredients
in **VICKS[®] NyQUIL^{®*}**

**MULTI-SYMPTOM
NITE TIME**

COLD & FLU NIGHTTIME RELIEF

ACETAMINOPHEN, DEXTROMETHORPHAN HBr, DOXYLAMINE SUCCINATE

- **Pain Reliever**
- **Fever Reducer**
- **Cough Suppressant**
- **Antihistamine**

10 SOFTGELS

Liquid filled capsules

<p>Drug Facts (continued)</p> <p>When using this product ■ do not use more than directed</p> <p>marked drowsiness may occur</p> <p>avoid alcoholic drinks</p> <p>be careful with driving a motor vehicle or operating machinery</p> <p>alcohol, sedatives and tranquilizers may increase drowsiness</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> fever gets worse or lasts more than 7 days pain or cough 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 <p>These could be signs of a serious condition</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children.</p> <p>Overdose warning: Taking more than the recommended dose 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 as well as for children, even if you do not notice any signs or symptoms.</p> <p>Directions ■ Take only as recommended—see Overdose warning. ■ do not exceed 4 doses per 24 hours</p> <p>adults and children 12 years of age swallow 2 softgels with water every 6 hours</p> <p>children 4 to under 12 years of age ask a doctor</p> <p>children under 4 years of age do not use</p> <p>If taking Nighttime and Daytime softgels carefully read each label to insure correct dosing</p> <p>Other Information</p> <p>■ store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat</p> <p>■ this product does not contain phenylpropranolamine</p>	
<p>Drug Facts</p> <p>Active ingredients (in each softgel)</p> <p>Acetaminophen 325 mg.....Pain reliever/fever reducer</p> <p>Dextromethorphan Hydrobromide 15 mg.....Cough suppressant</p> <p>Doxylamine Succinate 6.25 mg.....Antihistamine</p> <p>Uses temporarily relieves common cold/flu symptoms: ■ cough due to minor throat and bronchial irritation ■ sore throat ■ headache ■ minor aches/pains ■ fever ■ runny nose and sneezing</p> <p>Warnings</p> <p>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.</p> <p>■ with other drugs containing acetaminophen</p> <p>■ 3 or more alcoholic drinks every day while using this product</p> <p>Sore throat warning: If sore throat is severe, lasts for more than 2 days, or occurs with or is followed by fever, headache, rash, nausea, or vomiting, see a doctor promptly.</p> <p>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.</p> <p>■ 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.</p> <p>■ to make a child sleep</p> <p>Ask a doctor before use if you have ■ liver disease ■ glaucoma ■ cough that occurs with too much phlegm (mucus) ■ a breathing problem or chronic cough ■ hiccups or asthma, chronic bronchitis, or emphysema ■ trouble urinating due to enlarged prostate gland</p> <p>Ask a doctor or pharmacist before use if you are ■ taking sedatives or tranquilizers ■ taking the blood-thinning drug warfarin.</p>	

VALUMEDS  MULTI-SYMPTOM NITE TIME

VALUMEDS  SEE NEW WARNINGS INFORMATION

Compare to the active ingredients in VICKS® NYQUIL®.

MULTI-SYMPTOM NITE TIME

COLD & FLU NIGHTTIME RELIEF

ACETAMINOPHEN, DEXTROMETHORPHAN HBr, DOXYLAMINE SUCCINATE

Manufactured and distributed by Procter & Gamble, owner of the registered trademarks Vicks® NyQuil®

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


Drug Facts (continued)

Inactive ingredients D&C Yellow No. 10, FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol, purified water, sorbitol sorbitan, titanium dioxide

Questions or comments? 1-888-333-9792

glycol 400, povidone,

- Pain Reliever
- Fever Reducer
- Cough Suppressant
- Antihistamine




10 SOFTGELS
Liquid filled capsules

*This product is not manuf
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EXP:

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

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ACETAMINOPHEN DEXTROMETHORPHAN HYDROBROMIDE AND DOXYLAMINE SUCCINATE

acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59105-005
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DOXYLAMINE SUCCINATE (UNII: V9B19B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONES (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KO0R)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	GREEN	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	215
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59105-005-10	1 in 1 CARTON		
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(59105-005)

Revised: 11/2014

J.P. BUSINESS ENTERPRISE