DAYTIME NIGHTTIME COLD AND FLU RELIEF MULTI-SYMPTOMacetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl BJWC (Berkley & Jensen / BJ's)

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.

Drug Facts

Active ingredients in Daytime (in each softgel) Acetaminophen 325 mg

Dextromethorphan HBr 10 mg Phenylephrine HCl 5 mg

Active ingredients in Nighttime (in each softgel) Acetaminophen 325 mg

Dextromethorphan HBr 15 mg Doxylamine succinate 6.25 mg

Purpose for Daytime Pain reliever/fever reducer

Cough suppressant Nasal decongestant

Purpose for Nighttime Pain reliever/fever reducer

Cough suppressant Antihistamine

Uses

DAYTIME

- temporarily relieves common cold and flu symptoms
 - cough due to minor throat and bronchial irritation
 - nasal congestion
 - headache

- minor aches and pains
- fever
- sore throat

NIGHTTIME

- temporarily relieves common cold and fly symptoms
 - o cough due to minor throat and bronchial irritation
 - sore throat
 - headache
 - minor aches and pain
 - fever
 - runny nose and sneezing

Warnings

DAYTIME and NIGHTTIME

Liver warning: These products contain acetaminophen. 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

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

DAYTIME and NIGHTTIME

- 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

DAYTIME

- liver disease
- heart disease

- diabetes
- thyroid disease
- high blood pressure
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to an enlarged prostate gland
- · persistent or chronic cough such as occurs with smoking, asthma, or emphysema

NIGHTTIME

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

Ask a doctor or pharmacist before use if you are

DAYTIME

taking the blood thinning drug warfarin

NIGHTTIME

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

When using this product,

DAYTIME

do not exceed recommended dosage.

NIGHTTIME

- excitability may occur, especially in children
- avoid alcoholic drinks
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

DAYTIME

- nervousness, dizziness or sleeplessness occur
- pain, cough, and nasal congestion 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.

NIGHTTIME

- 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,

DAYTIME NIGHTTIME

ask a health professional before use.

Keep out of reach of children.

DAYTIME and NIGHTTIME

Overdose warning: Taking more than the recommended dose can cause liver damage. 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

DAYTIME

- do not take more than directed (see Overdose warning)
- do not take more than 4 doses in 24 hours
- swallow whole; do not crush, chew, or dissolve
- adults and children 12 years and over: take 2 softgels with water every 4 hours
- children under 12 years : do not use

Nighttime:

- do not take more than directed (see Overdose warning)
- do not take more than 4 doses in 24 hours
- swallow whole; do not crush, chew, or disolve
- adults and children 12 years and over: take 2 softgels with water every 6 hours
- children under 12 years: do not use

Other information

DAYTIME and NIGHTTIME

- store between 15°-30°C (59°-86°F)
- avoid excessive heat

Inactive ingredients

Daytime butylated hydroxyanisole, butylated hydroxytoluene, FD&C red #40*, FD&C yellow #6*, gelatin, glycerin, polyethylene glycol*, povidone, propylene glycol, purified water, sorbitan*, sorbitol, titanium dioxide*, white ink

^{*}contain one or more of these ingredients

Nighttime D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan*, sorbitol, titanium dioxide*, white ink

*may contain this ingredient

Questions or comments?

Call toll free 1-800-934-1204 Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredients in Vicks® Dayquil® and Nyquil® Cold & Flu LiquiCaps®†

DAYTIME

MULTI-SYMPTOM

COLD & FLU RELIEF

Acetaminophen - Pain Reliever / Fever Reducer

Dextromethorphan HBr - Cough Suppressant

Phenylephrine HCI - Nasal Decongestant

NON-DROWSY

Alcohol-Free

Antihistamine-Free

SOFTGELS**

(**LIQUID-FILLED CAPSULES)

NIGHTTIME

MULTI-SYMPTOM

COLD & FLU RELIEF

Liquid Capsules

Acetaminophen - Pain Reliever / Fever Reducer

Dextromethorphan HBr - Cough Suppressant

Doxylamine Succinate - Antihistamine

SOFTGELS**

(**LIQUID-FILLED CAPSULES)

When using Daytime and Nighttime products, carefully read the labeling to ensure correct dosing.

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and Gamble Company.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

Distributed by:

BJ's Wholesale Club

25 Research Drive

Westborough, MA 01581

Product Label



DAYTIME NIGHTTIME COLD AND FLU RELIEF MULTI-SYMPTOM

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68391-744

Packa	aging	

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:68391-744-72	1 in 1 KIT; Type 0: Not a Combination Product	06/30/2018	12/27/2024

Quantity of Parts

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Part #	Package Quantity	Total Product Quantity		
Part 1	24 BLISTER PACK	24		
Part 2	48 BLISTER PACK	48		

Part 1 of 2

NIGHTTIME COLD FLU RELIEF MULTI-SYMPTOM

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg		
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg		
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg		

Inactive Ingredients			
Ingredient Name	Strength		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POVIDONE (UNII: FZ 989GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITAN (UNII: 6092ICV9RU)			

SORBITOL (UNII: 506T60A25R)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics				
Color	green	Score	no score	
Shape	CAPSULE	Size	20mm	
Flavor		Imprint Code	P30;94A;P120;AS017	
Contains				

P	Packaging				
#	# Item Package Description		Marketing Start Date	Marketing End Date	
1		24 in 1 CARTON			
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
OTC monograph final	part341	06/30/2018	12/27/2024	

Part 2 of 2

DAYTIME COLD FLU RELIEF MULTI-SYMPTOM

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg		
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		

Inactive Ingredients	
Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6092ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	orange	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	P19;95A;512;AS016
Contains			

Packaging							
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date			
1		48 in 1 CARTON					
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 final	part341	06/30/2018	12/27/2024					

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph final	part341	06/30/2018	12/27/2024				

Labeler - BJWC (Berkley & Jensen / BJ's) (159082692)