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

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#### **DRUG FACTS**

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

Dextromethorphan HBr 10 mg Phenylephrine HCl 5 mg

## Active ingredients for 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 flu symptoms
  - cough due to minor throat and bronchial irritation
  - sore throat
  - headache
  - minor aches and pains
  - fever
  - runny nose and sneezing

## **Warnings**

#### **DAYTIME**

**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 these products

**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.

#### **NIGHTTIME**

**Liver warning:** This product 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

Alergy 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 following by fever, headache, rash, nausea, vomiting, consult a doctor promptly.

#### Do not use

**DAYTIME** 

- 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.

#### **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 such as occurs 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**

- do not exceed recommended dosage
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- 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
- redness or swelling is present
- new symptoms occur
- fever gets worse or lasts more than 3 days
- · 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 headache that lasts.

These could be a 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 liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 dissolve
- adults and children 12 years and over: take 2 softgels with water every 6 hours
- children under 12 years: do not use

#### Other information

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

## **Inactive ingredients**

#### **DAYTIME**

butylated hydroxyanisole, butylated hydroxytoluene, FD&C yellow #6, gelatin, glycerin, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, white ink

## **NIGHTTIME**

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

## Questions or comments?

Call toll free1-800-934-1204 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 Congestant

**NON-DROWSY** 

Alcohol-Free

Antihistamine-Free

SOFTGELS\*\*

(\*\* LIQUID-FILLED CAPSULES)

# When using Daytime and Nighttime products, carefully read the labelling to ensure correct dosing

### **NIGHTTIME**

**MULTI-SYMPTOM** 

**COLD & FLU RELIEF** 

Acetaminophen - Pain Reliever / Fever Reducer

Dextromethorphan HBr - Cough Suppressant

Doxylamine succinate - Antihistamine

SOFTGELS\*\*

(\*\*LIQUID-FILLED CAPSULES)

†This product is not manufactured or distributed by The Procter & Gamble Company. Vicks®, DayQuil, NyQuil®, and LiquiCaps® are registered

trademarks of the Procter and Gamble Company.

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

## KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Distributed by:

BJ's Wholesale Club

25 Research Drive

Westborough, MA 01581

## **Product Label**



BERKLEY JENSEN BJ'S Daytime Nighttime Multi-Symptom Cold & Flu Relief

## DAYTIME NIGHTTIME COLD FLU RELIEF MULTI SYMPTOM

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68391-850

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:68391-850- 72	1 in 1 KIT; Type 0: Not a Combination Product	10/30/2019	12/31/2024	

Quant	Quantity of Parts				
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**

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			
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (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)

MANNITOL (UNII: 30WL53L36A)

Product Characteristics				
Color green Score no score				
Shape	CAPSULE	Size	20mm	
Flavor		Imprint Code	P30	
Contains				

Pa	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 Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	10/30/2019	12/31/2024	

## 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		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		

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

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
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)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics				
Color orange Score no score				
Shape	CAPSULE	Size	20mm	
Flavor		Imprint Code	P19	
Contains				

Pa	Packaging					
#	# Item 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 Drug	M012	10/30/2019	12/31/2024	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	10/30/2019	12/31/2024	

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

Revised: 12/2023 BJWC (Berkley & Jensen / BJ's)