

DAYTIME NIGHTTIME COLD/FLU- acetaminophen, 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

temporarily relieves common cold and flu symptoms:

- sore throat
- headache
- minor aches and pains
- fever
- cough due to minor throat and bronchial irritation
- nasal congestion (Daytime only)
- runny nose and sneezing (Nighttime only)

Warnings

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

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

Do not use

- to make a child sleep (Nighttime only)
- 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
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, emphysema, and (for Nighttime only) chronic bronchitis
- glaucoma (Nighttime only)
- diabetes (Daytime only)
- heart disease (Daytime only)
- thyroid disease (Daytime only)
- high blood pressure (Daytime only)

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers (Nighttime only)

When using this product

- **do not exceed recommended dosage**

In addition, when using 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

- nervousness, dizziness, or sleeplessness occur (Daytime only)
- pain, cough, and (for Daytime only) 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.

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 right away. Quick medical attention is critical for adults and for children even if you do not notice any signs or symptoms.

Directions

- **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
- **Daytime:** adults and children 12 years and over: take 2 softgels with water every 4 hours
- **Nighttime:** 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 at room temperature 15°-30°C (59°-86°F)
- avoid excessive heat

Inactive ingredients

Inactive ingredients in Daytime butylated hydroxyanisole, butylated hydroxytoluene, edible white ink, FD&C Red #40*, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, and sorbitol

*may contain this ingredient

Inactive ingredients in Nighttime D&C Yellow #10, edible white ink, FD&C Blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol

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® LiquiCaps®†

DAYTIME

Multi-Symptom

Cold & Flu Relief

Acetaminophen-Aches/Fever/Sore Throat

Dextromethorphan HBr-Cough

Phenylephrine HCl-Nasal Congestion

Non-Drowsy

Alcohol-Free

Antihistamine-free

Softgels**

(**Liquid-filled capsules)

NIGHTTIME

Multi-symptom

Cold & Flu Relief

Acetaminophen-Aches/Fever/Sore Throat

Dextromethorphan HBr- Cough

Doxylamine succinate-Runny nose/sneezing

Softgels**

(**Liquid-filled capsules)

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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

†This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® DayQuil® and NyQuil® LiquiCaps®.

Distributed by:


BJ's Wholesale Club

25 Research Drive

Westborough, MA 01581

Product Label

0 3 2 8 1 2 1 1



Drug Facts (continued)

Warnings: These products contain acetaminophen. Serious liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours. Do not take more than 2 capsules every 4 hours with this product. Do not take more than 2 capsules every 4 hours with any other drug containing acetaminophen (prescription or over-the-counter). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. Do not take more than 2 capsules every 4 hours with any other drug containing acetaminophen (prescription or over-the-counter), or if you have liver disease, or if you are taking other drugs for depression, epilepsy, or mental health conditions, or if you are taking other drugs for pain, or if you are taking other drugs for colds, coughs, or allergies.

Directions: See the back of the box for directions. Do not take more than 2 capsules every 4 hours with this product. Do not take more than 2 capsules every 4 hours with any other drug containing acetaminophen (prescription or over-the-counter). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. Do not take more than 2 capsules every 4 hours with any other drug containing acetaminophen (prescription or over-the-counter), or if you have liver disease, or if you are taking other drugs for depression, epilepsy, or mental health conditions, or if you are taking other drugs for pain, or if you are taking other drugs for colds, coughs, or allergies.

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berkley jensen.

DAYTIME

MULTI-SYMPTOM COLD & FLU RELIEF

Acetaminophen - Aches/Fever/Sore Throat
Dextromethorphan HBr - Cough
Phenylephrine HCl - Nasal Congestion

NON-DROWSY
Alcohol-Free
Antihistamine-Free



ACTUAL SIZE

48 SOFTGELS**
(**LIQUID-FILLED CAPSULES)

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NIGHTTIME

MULTI-SYMPTOM COLD & FLU RELIEF

Acetaminophen - Aches/Fever/Sore Throat
Dextromethorphan HBr - Cough
Doxylamine succinate - Runny Nose/Sneezing



ACTUAL SIZE

24 SOFTGELS**
(**LIQUID-FILLED CAPSULES)

72 TOTAL SOFTGELS

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

berkley jensen.

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MULTI-SYMPTOM COLD & FLU RELIEF

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(**LIQUID-FILLED CAPSULES)

72 TOTAL SOFTGELS

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Lot No.:
Exp. Date:

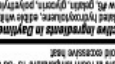
berkley jensen.

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24 SOFTGELS**
(**LIQUID-FILLED CAPSULES)

72 TOTAL SOFTGELS

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Lot No.:
Exp. Date:

BJ's Daytime and Nighttime Cold and Flu Relief Softgels

DAYTIME NIGHTTIME COLD/FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information

| | | | |
|--------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68391-490 |
|--------------|----------------|--------------------|---------------|

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:68391-490-72 | 1 in 1 CARTON; Type 0: Not a Combination Product | | |

Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|--------|------------------|------------------------|
| Part 1 | 4 BLISTER PACK | 48 |
| Part 2 | 2 BLISTER PACK | 24 |

Part 1 of 2

DAYTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule

Product Information

| | |
|-------------------------|------|
| 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 | 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 GLYCOLS (UNII: 3WJQ0SDW1A) | |
| POVIDONES (UNII: FZ989GH94E) | |

| | |
|--|--|
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SORBITAN (UNII: 6O92ICV9RU) | |
| SORBITOL (UNII: 506T60A25R) | |

Product Characteristics

| | | | |
|-----------------|---------|---------------------|-------------|
| Color | ORANGE | Score | no score |
| Shape | CAPSULE | Size | 20mm |
| Flavor | | Imprint Code | P19;95A;36A |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---|----------------------|--------------------|
| 1 | | 12 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 | | |

Part 2 of 2

NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule

Product Information

| | |
|--------------------------------|------|
| 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: 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 GLYCOLS (UNII: 3WJQ0SDW1A) | |
| POVIDONES (UNII: FZ989GH94E) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SORBITAN (UNII: 6O92ICV9RU) | |
| SORBITOL (UNII: 506T60A25R) | |

Product Characteristics

| | | | |
|-----------------|---------|---------------------|-------------|
| Color | GREEN | Score | no score |
| Shape | CAPSULE | Size | 20mm |
| Flavor | | Imprint Code | P30;94A;35A |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---|----------------------|--------------------|
| 1 | | 12 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 | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part341 | 01/15/2013 | |

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