

**DAYTIME NIGHTTIME COLD AND FLU RELIEF MULTI-SYMP TOM-
acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine
hcl**

WinCo Foods, LLC

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 flu symptoms
 - 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

- **do not exceed recommended dosage**
- 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,

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 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

DAYTIME and NIGHTTIME

- 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 **1-800-824-1706** Monday-Friday 9AM-4PM MST

Principal Display Panel

†Compare to the active ingredients in VICKS® DAYQUIL® & NYQUIL® Cold & Flu LiquiCaps®

MULTI-SYMPTOM COLD & Flu Relief

NON-DROWSY

Daytime

ACETAMINOPHEN / PAIN RELIEVER - FEVER REDUCER

DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT

PHENYLEPHRINE HCL / NASAL DECONGESTANT

Relieves: Aches, Fever, Sore Throat, Cough & Nasal Congestion

Non-drowsy, Alcohol-free, Antihistamine-free

softgels**

**Liquid-Filled Capsules

Nighttime

ACETAMINOPHEN / PAIN RELIEVER - FEVER REDUCER

DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT

DOXYLAMINE SUCCINATE / ANTIHISTAMINE

Relieves: Aches, Fever, Sore Throat, Cough, Sneezing & Runny Nose

Alcohol-free

Softgels

**Liquid-Filled Capsules

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

†This product is not manufactured or distributed by The Procter & Gamble Company. Vicks®, DayQuil®, NyQuil®, and LiquiCap® 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 SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY:

WINCO FOODS, LLC,
BOISE, ID 83704
www.wincofoods.com

Product Label



Compare to the active ingredients in VICKS® DAYQUIL® & NYQUIL® Cold & Flu LiquiCaps®

NON-DROWSY
Daytime
ACETAMINOPHEN/
PAIN RELIEVER - FEVER REDUCER
DXTROMETHORPHAN HBr/
COUGH SUPPRESSANT
PHENYLEPHRINE HCl/
NASAL DECONGESTANT

Relieves: Aches, Fever, Sore Throat,
 Cough & Nasal Congestion
 Non-drowsy, Alcohol-free, Antihistamine-free



**Liquid-Filled Capsules

Daytime Cold & Flu Softgel

Drug Facts

Purposes

- Acetaminophen 325 mg.....Pain reliever/fever reducer
- Dextromethorphan HBr 10 mg.....Cough suppressant
- Phenylephrine HCl 5 mg.....Nasal decongestant

Uses

- 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

Warnings

- Liver warning: This product contains 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 redness
 - hives
 - blistering
 - itching
 - swelling
 - skin peeling
 - fever
 - skin 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

- 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.

Drug Facts (continued)

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- diabetes
- kidney disease
- triple beam scale
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to an enlarged prostate gland
- asthma, chronic bronchitis, or emphysema

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

When using this product, do not exceed recommended dosage.

Stop use and ask a doctor if

- nervousness, dizziness, or sleepiness occur
- pain, cough, or 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.

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

- do not take more than directed (see Overdose warning)
- 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 Cold & Flu Softgel

Drug Facts

Purposes

- Acetaminophen 325 mg.....Pain reliever/fever reducer
- Dextromethorphan HBr 15 mg.....Cough suppressant
- Doxylamine succinate 6.25 mg.....Antihistamine

Uses

- 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 & sneezing

Warnings

- Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:
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 - 3 or more alcoholic drinks every day while using this product
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 - skin redness
 - hives
 - blistering
 - itching
 - swelling
 - skin peeling
 - fever
 - skin 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

- 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.

Drug Facts (continued)

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 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 taking the blood thinning drug warfarin.

When using this product, do not exceed recommended dosage.

Stop use and ask a doctor if

- 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
 - gait 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
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Daytime Cold & Flu Softgel

Drug Facts (continued)

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- heart disease
- high blood pressure
- diabetes
- kidney disease
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Nighttime Cold & Flu Softgel

Drug Facts (continued)

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 such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to an enlarged prostate gland

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PLD-05704 FC006976 W17806

Comments & Questions?
800-824-1706
www.wincofoods.com

100% SATISFACTION GUARANTEE

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BOISE, ID 83704

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| | |
|---|---|
| <p>Daytime Cold & Flu Softgel</p> <p>Drug Facts (continued)</p> <p>Other information</p> <ul style="list-style-type: none"> ■ store between 15-30°C (59-86°F) ■ avoid excessive heat <p>Inactive ingredients butylated hydroxytoluene, butylated hydroxytoluene, FD&C yellow #6, gelatin, glycerin, mannitol, polyethylene glycol, polyethylene glycol, purified water, sorbitan, sorbitol, white ink</p> <p>Questions or comments?</p> <p>Call 800-824-1706 Monday - Friday 9am - 4pm MST</p> | <p>Nighttime Cold & Flu Softgel</p> <p>Drug Facts (continued)</p> <p>Other information</p> <ul style="list-style-type: none"> ■ store between 15-30°C (59-86°F) ■ avoid excessive heat <p>Inactive ingredients D&C yellow #10, FD&C blue #1, gelatin, glycerin, mannitol, polyethylene glycol, polyethylene glycol, purified water, sorbitan, sorbitol, white ink</p> <p>Questions or comments?</p> <p>Call 800-824-1706 Monday - Friday 9am - 4pm MST</p> |
|---|---|

WINCO FOODS Daytime Nighttime Cold & Flu Relief

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:67091-336 |
|---------------------|----------------|---------------------------|---------------|

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:67091-336-48 | 1 in 1 KIT; Type 0: Not a Combination Product | 06/01/2019 | |

Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|--------|------------------|------------------------|
| Part 1 | 16 BLISTER PACK | 16 |

| | | |
|---------------|-----------------|----|
| Part 2 | 32 BLISTER PACK | 32 |
|---------------|-----------------|----|

Part 1 of 2

NIGHTTIME COLD AND 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: 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 GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POVIDONE (UNII: FZ989GH94E) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SORBITAN (UNII: 6O92ICV9RU) | |
| SORBITOL (UNII: 506T60A25R) | |
| MANNITOL (UNII: 3OWL53L36A) | |

Product Characteristics

| | | | |
|-----------------|---------------|---------------------|----------|
| Color | green (Clear) | Score | no score |
| Shape | CAPSULE | Size | 20mm |
| Flavor | | Imprint Code | P30 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
| 1 | | 16 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 | 06/01/2019 | |

Part 2 of 2

DAYTIME COLD AND FLU RELIEF

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 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: 6O92ICV9RU) | |
| SORBITOL (UNII: 506T60A25R) | |
| MANNITOL (UNII: 3OWL53L36A) | |

Product Characteristics

| | | | |
|--------------|----------------|--------------|----------|
| Color | orange (Clear) | Score | no score |
| Shape | CAPSULE | Size | 20mm |

| | | | |
|-----------------|--|---------------------|-----|
| Flavor | | Imprint Code | P19 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 | | 32 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 | 06/01/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 06/01/2019 | |

Labeler - WinCo Foods, LLC (056098817)