

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

CVS Pharmacy

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.

CVS Pharmacy, Inc. Daytime Nighttime Cold & Flu Relief Drug Facts

Nighttime Cold & Flu

Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Uses

temporarily relieves common cold/flu symptoms:

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

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 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

- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

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

When using this product

- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when 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: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 directed – see Overdose warning
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

| | |
|---------------------------------|-------------------|
| adults & children 12 yrs & over | 30 mL every 6 hrs |
| children 4 to under 12 yrs | ask a doctor |
| children under 4 yrs | do not use |

Other information

- each 30 mL contains: sodium 38 mg
- store at 20-25°C (68-77°F)

Inactive Ingredients

alcohol, anhydrous citric acid, D&C yellow no. 10, FD&C green no. 3, FD&C yellow no. 6, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions or comments?

1-800-719-9260

Daytime Cold & Flu

Active ingredients (in each 15 mL)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves common cold/flu symptoms:
- nasal congestion
- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 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

- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin

When using this product

do not use more than directed

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, nasal congestion or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- 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.

Directions

- take only as directed – see Overdose warning
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

| | |
|---------------------------------|-------------------|
| adults & children 12 yrs & over | 30 mL every 4 hrs |
| children 6 to under 12 yrs | 15 mL every 4 hrs |
| children 4 to under 6 yrs | ask a doctor |
| children under 4 yrs | do not use |

Other information

- each 15 mL contains: sodium 7 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

butylated hydroxyanisole, edetate disodium, FD&C yellow no. 6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum

Questions or comments?

1-800-719-9260

Principal Display Panel

TWIN PACK!

Compare to the active ingredients in Vicks® NyQuil® Cold & Flu

Cold/Flu

Non-Drowsy

Daytime

COLD & FLU RELIEF

Powerful Non-Drowsy Relief

ACETAMINOPHEN

Pain reliever; Fever reducer

DEXTROMETHORPHAN HBr

Cough suppressant

PHENYLEPHRINE HCl

Nasal decongestant

Relieves:

Aches; Fever; Cough; Nasal congestion

Alcohol free

Antihistamine free

See New Warnings

TOTAL 24 FL OZ (1.5 PT) (710 mL)

Compare to the active ingredients in Vicks® DayQuil® Cold & Flu

Cold/Flu

Multi-Symptom

Nighttime

COLD & FLU RELIEF

Powerful Nighttime Relief

ACETAMINOPHEN

Pain reliever; Fever reducer

DEXTROMETHORPHAN HBr

Cough suppressant

DOXYLAMINE SUCCINATE

Antihistamine

Relieves:

Aches; Cough; Sneezing; Fever & Sore throat; Runny nose

Original Flavor

ALCOHOL 10%

See New Warnings

TWO 12 FL OZ (355 mL) UNITS

TWIN PACK!



Compare to the active ingredients in Vicks® DayQuil® Cold & Flu*

Cold/Flu

Non-Drowsy

Daytime COLD & FLU RELIEF

Powerful Non-Drowsy Relief

ACETAMINOPHEN
Pain reliever; Fever reducer
DEXTROMETHORPHAN HBr
Cough suppressant
PHENYLEPHRINE HCl
Nasal decongestant

Relieves:
Aches; Fever; Cough;
Nasal congestion



Alcohol free
Antihistamine free
See New Warnings

TOTAL 24 FL OZ (1.5 PT) (710 mL)



Compare to the active ingredients in Vicks® NyQuil® Cold & Flu*

Cold/Flu

NDC 59779-567-02

Multi-Symptom

Nighttime COLD & FLU RELIEF

Powerful Nighttime Relief

ACETAMINOPHEN
Pain reliever; Fever reducer
DEXTROMETHORPHAN HBr
Cough suppressant
DOXYLAMINE SUCCINATE
Antihistamine

Relieves:
Aches; Cough; Sneezing;
Fever & Sore throat;
Runny nose



Original Flavor
ALCOHOL 10%
See New Warnings

TWO 12 FL OZ (355 mL) UNITS

PARENTS:
Learn about teen medicine abuse
www.StopIllicitDrugs.org

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING
*These products are not manufactured or distributed by Procter & Gamble, distributor of Vicks® DayQuil® Cold & Flu and Vicks® NyQuil® Cold & Flu.

Drug Facts (continued)
Inactive ingredients: butylated hydroxyanisole, edetate disodium, FD&C yellow no. 6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum.
Questions or comments? 1-800-719-9280



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V-16-430

Drug Facts (continued)
Inactive ingredients: alcohol, anhydrous citric acid, D&C yellow no. 10, FD&C green no. 3, FD&C yellow no. 6, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate.
Questions or comments? 1-800-719-9280

| Drug Facts | Nighttime Cold & Flu |
|--|-----------------------------|
| Active ingredients (in each 30 mL) | Purpose |
| Acetaminophen 650 mg..... | Pain reliever/fever reducer |
| Dextromethorphan HBr 30 mg..... | Cough suppressant |
| Doxylamine succinate 1.25 mg..... | Antihistamine |
| Uses temporarily relieves common cold/flu symptoms: ■ cough due to minor throat and bronchial irritation ■ sore throat ■ headache ■ minor aches and pains ■ fever ■ runny nose and sneezing | |
| 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 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 ■ 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. ■ if you have ever had an allergic reaction to this product or any of its ingredients | |
| Ask a doctor before use if you have ■ liver disease ■ glaucoma ■ cough that occurs with too much phlegm (mucus) ■ trouble urinating due to an enlarged prostate gland ■ a breathing problem such as emphysema or chronic bronchitis ■ persistent or chronic cough as occurs with smoking, asthma, or emphysema ■ a sodium-restricted diet | |
| Ask a doctor or pharmacist before use if you are ■ taking sedatives or tranquilizers ■ taking the blood thinning drug warfarin | |
| When using this product ■ excitability may occur, especially in children ■ marked drowsiness may occur ■ avoid alcoholic drinks ■ be careful when 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: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 directed—see Overdose warning ■ only use the dose cup provided ■ do not exceed 4 doses per 24 hrs adults & children 12 yrs & over 30 mL every 6 hrs children 6 to under 12 yrs 15 mL every 6 hrs children 4 to under 6 yrs ask a doctor children under 4 yrs do not use | |
| Other information ■ each 30 mL contains sodium 38 mg ■ store at 20-25°C (68-77°F) | |

| Drug Facts | Daytime Cold & Flu |
|---|-----------------------------|
| Active ingredients (in each 15 mL) | Purpose |
| Acetaminophen 325 mg..... | Pain reliever/fever reducer |
| Dextromethorphan HBr 10 mg..... | Cough suppressant |
| Phenylephrine HCl 15 mg..... | Nasal decongestant |
| Uses temporarily relieves common cold/flu symptoms: ■ cough due to minor throat and bronchial irritation ■ sore throat ■ headache ■ minor aches and pains ■ fever ■ nasal congestion | |
| Warnings Liver warning: This product contains acetaminophen. Severe liver damage may occur if ■ adult takes more than 4,000 mg of acetaminophen in 24 hours ■ child takes more than 5 doses in 24 hours ■ taken with other drugs containing acetaminophen ■ adult has 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 ■ 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. ■ if you have ever had an allergic reaction to this product or any of its ingredients | |
| Ask a doctor before use if you have ■ liver disease ■ heart disease ■ thyroid disease ■ high blood pressure ■ trouble urinating due to an enlarged prostate gland ■ cough that occurs with too much phlegm (mucus) ■ persistent or chronic cough such as occurs with smoking, asthma, or emphysema ■ diabetes | |
| Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin | |
| When using this product, do not use more than directed | |
| Stop use and ask a doctor if ■ you get nervous, dizzy or lightheaded ■ pain, nasal congestion or cough gets worse or lasts more than 5 days (children) or 7 days (adults) ■ 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: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 directed—see Overdose warning ■ only use the dose cup provided ■ do not exceed 4 doses per 24 hrs adults & children 12 yrs & over 30 mL every 4 hrs children 6 to under 12 yrs 15 mL every 4 hrs children 4 to under 6 yrs ask a doctor children under 4 yrs do not use | |
| Other information ■ each 15 mL contains sodium 7 mg ■ store at 20-25°C (68-77°F) | |

DAYTIME NIGHTTIME MULTI SYMPTOM COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information

| | | | |
|--------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:59779-567 |
|--------------|----------------|--------------------|---------------|

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:59779-567-02 | 1 in 1 CARTON; Type 0: Not a Combination Product | 07/27/2012 | |

Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|--------|------------------|------------------------|
| Part 1 | 1 BOTTLE | 355 mL |
| Part 2 | 1 BOTTLE | 355 mL |

Part 1 of 2

NIGHTTIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

Product Information

| | |
|-------------------------|------|
| Route of Administration | ORAL |
|-------------------------|------|

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------------|---------------------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 650 mg in 30 mL |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 30 mg in 30 mL |
| DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) | DOXYLAMINE SUCCINATE | 12.5 mg in 30 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALCOHOL (UNII: 3K9958V90M) | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S) | |
| POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A) | |

| | |
|-------------------------------------|--|
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | |

Product Characteristics

| | | | |
|----------|---------------------------------------|--------------|--|
| Color | GREEN (clear, bright green) | Score | |
| Shape | | Size | |
| Flavor | FRUIT (anise / cooling menthol aroma) | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---|----------------------|--------------------|
| 1 | | 355 mL in 1 BOTTLE; 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 | 08/16/2011 | |

Part 2 of 2

DAYTIME

acetaminophen, dextromethorphan hbr, phenylephrine hcl solution

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 in 15 mL |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg in 15 mL |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg in 15 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |

| | |
|---|--|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JH2SW) | |
| POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0K00R) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| SUCROSE (UNII: C151H8M554) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| MENTHOL (UNII: L7T10EIP3A) | |

Product Characteristics

| | | | |
|-----------------|--------------------------------------|---------------------|--|
| Color | ORANGE (clear) | Score | |
| Shape | | Size | |
| Flavor | MENTHOL (strong menthol, weak fruit) | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---|----------------------|--------------------|
| 1 | | 355 mL in 1 BOTTLE; 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 | 06/09/2006 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 07/27/2012 | |

Labeler - CVS Pharmacy (062312574)