# CAREONE DAYTIME NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl American Sales Company

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.

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# American Sales Company Daytime Nighttime Cold & Flu 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 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 39 mg
- store at 20-25°C (68-77°F)

# Inactive ingredients

alcohol, anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, 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
- high blood pressure
- thyroid disease
- diabetes
- · 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

# 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.

# 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)

# **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

# Package/Label Principal Display Panel

**COMBINATION PACK** 

CAREone<sup>®</sup>

Compare to the active ingredients in Vicks<sup>®</sup> DayQuil<sup>®</sup> Cold & Flu

**DAYTIME COLD & FLU** 

Pain Reliever/Fever Reducer-Acetaminophen

Cough Suppressant-Dextromethorphan HBr

Nasal Decongestant-Phenylephrine HCI

Powerful Non-Drowsy Relief

Alcohol Free

Relieves:

Aches, Fever, Sore Throat

**Nasal Congestion** 

Cough

**OUR PHARMACISTS RECOMMEND** 

Original Flavor

12 FL OZ (355mL) (Day)

CAREone<sup>®</sup>

Compare to the active ingredients in Vicks  $^{\circledR}$  NyQuil  $^{\circledR}$  Cold & Flu

NIGHTTIME COLD & FLU

Pain Reliever/Fever Reducer-Acetaminophen

Cough Suppressant-Dextromethorphan HBr

Antihistamine-Doxylamine Succinate

Powerful Nighttime Relief

10% ALCOHOL

Relieves:

Aches & Fever

Runny Nose

Sneezing

Cough

**OUR PHARMACISTS RECOMMEND** 

Cherry Flavor

12 FL OZ (355mL) (Night)

# **COMBINATION PACK**



Compare to the active ingredients in Vicks ® Day Quil ® Cold & Flu\*



Compare to the active ingredients in Vicks<sup>®</sup> NyQuil<sup>®</sup> Cold & Flu\*

#### 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 & Ru and NyQuil® Cold & Ru.

# DAYTIME COLD & FLU

Pain Reliever/Fever Reducer-Acetaminophen Cough Suppressant-Dextromethorphan HBr Nasal Decongestant-Phenylephrine HCI

# NIGHTTIME COLD & FLU

Pain Reliever/Fever Reducer-Acetaminophen Cough Suppressant-Dextromethorphan HBr Antihistamine-Doxylamine Succinate

## **Powerful Non-Drowsy Relief**

**Alcohol Free** 

Relieves: Aches, Fever, Sore Throat Nasal Congestion Cough





12 FL OZ (355mL) (Day)

## **Powerful Nighttime Relief**

10% ALCOHOL

Relieves: Aches & Fever Runny Nose Sneezing Cough





**Cherry Flavor** 

12 FL OZ (355mL) (Night)

PARENTS:
Learn about teen medicine abuse

www.StopMedicineAbuse.org

Gluten Free

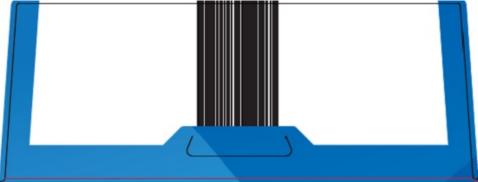
DISTRIBUTED BY: ADUSA DISTRIBUTION, LLC SALISBURY, NC 28147 1-933-992-3872

Quality guaranteed or your money back.





73302 OF C2



Daytime Cold & Fit

## **Drug Facts**

# Active ingredients (in each 30 mL)

Dextromethorphan HBr 30 mg. ...Cough suppressant Doxytamine succinate 12.5 mg.

- Uses temporarily relieves common cold/flu symptome.

  cough due to minor throat and bronchal intestion.

  sore throat.

  headache is minor aches and peins
  fever is runny nose and sareazing.

#### Warnings

Liver warning occur if you tal ing: This product contains acetaminophen. Severe liver diamage may

- more than 4,000 mg of acetaminophen in 24 hours

 with other drugs containing sceterrinophen
 3 or more alcoholic drinks every day while using this product
Allergy alert Acetamhophen may cause severe skin reactions. Symptoms may Include

m skin reddening ■ bilsters ■ rash
If a skin reaction occurs, stop use and seek medical help right ewery.
Sere throat warning: If soet throat is servere, persists for more thein 2 days, is accompanied or followed by fever, headsche, rash, nauses, or vomitting, consults doctor promptly.

### Do not use

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  If you are now lasting a prescription monoamhe coldase inhibitor (MACI)
  (certain drugs for depression, jesychibitic, or emotional conditions, or
  Parkinson's disease), or for 2 weeks after slopping the MACI drug. If you do not
  know if your pre-scription drug contains an MAOL ask a doctor or pharmaciet.
- 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

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  If ther disease is glacoma
  cough that occurs with too much phisgm (mucus)
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  trouble urheating due to an entanged prostate gland
  pendisert or chronic cough as occurs with smoking, asthma, or emphysema
  a sodium-restricted diet

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   These could be signs of a serious condition.

Trees could be agree of a serious constantion.

If pregnant or breast-feeding, ask a health professional belore use.

Keep out of reach of children. Overdose warning; in case of overdose, get
medical help or contact a Polson Control Center right every (1-800-222-1222).

Outok medical attention is critical for adults as well as for children even if you de not notice any signs or symptoms.

### Directions

|              | e dose cup provided  | ■ do not exceed 4 doses per 24 hrs |
|--------------|----------------------|------------------------------------|
| adults & ch  | ildrem 12 yrs & over | 30 mL every 6 hrs                  |
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| oblicken un  | doe 4 um             | do not uso                         |

## Other information

- each 30 mL contains: sodium 39 mg
   store at 20-25°C (68-77°F)

Imactive ingredients alcohol, enhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, flavor, high fructose com syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions or comments? 1-800-719-9260

## Drug Facts

Active ingredients (in each 15 mL) ...Pain reliever/fever reduce Dextromethorphan HBr 10 mg.... ....Cough suppressant ....Nasal decongestant Phenylephrine HCl 5 mg...

## Uses

- b temporarity relieves common cold\*iu sympitorins:

  in insaid congestion in cough due to militor throat and bronchial limitation

  in sore throat in headache in minor aches and pains in fever

## Warnings

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## Directions

■ take only as directed – see Overdose warning
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| 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 bulytated hydroxyanisole, edetale disodium, FD&C yellow no. 6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propytene glycol, purified water, sacchartn sodium, sucrose, xanthan gum

Questions or comments? 1-800-719-9260





acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41520-427

## **Packaging**

| ı |   |                      |  |                         |                       |
|---|---|----------------------|--|-------------------------|-----------------------|
|   | # | Item Code            | Package Description                              | Marketing Start<br>Date | Marketing End<br>Date |
|   |   | NDC:41520-427-<br>02 | 1 in 1 CARTON; Type 0: Not a Combination Product | 11/02/2016              |                       |

# **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

# **CAREONE NIGHT TIME COLD AND FLU**

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

## **Product Information**

 Item Code (Source)
 NDC:41520-084

 Route of Administration
 ORAL

# **Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength                | Strength            |
|--|----------------------------------|---------------------|
| ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)                           | ACETAMINOPHEN                    | 650 mg<br>in 30 mL  |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN<br>HYDROBROMIDE | 30 mg<br>in 30 mL   |
| <b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)                | DOXYLAMINE SUCCINATE             | 12.5 mg<br>in 30 mL |

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

ALCOHOL (UNII: 3K9958V90M)

| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)            |  |
|---|--|
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                  |  |
| FD&C RED NO. 40 (UNII: WZB9127XOA)                  |  |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)         |  |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) |  |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                 |  |
| WATER (UNII: 059QF0KO0R)                            |  |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY)                 |  |
| SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) |  |

| Product Characteristics |                        |              |  |
|-------------------------|------------------------|--------------|--|
| Color                   | RED (Clear/Dark Red)   | Score        |  |
| Shape                   |                        | Size         |  |
| Flavor                  | CHERRY (Menthol Aroma) | Imprint Code |  |
| Contains                |                        |              |  |

| 1 | P | Packaging            |   |                         |                       |
|---|---|----------------------|---|-------------------------|-----------------------|
|   | # | Item Code            | Package Description                                   | Marketing Start<br>Date | Marketing End<br>Date |
|   |   | NDC:41520-084-<br>40 | 355 mL in 1 BOTTLE; Type 0: Not a Combination Product |                         |                       |

| Marketing Information |                         |                       |  |
|-----------------------|-------------------------|-----------------------|--|
| Marketing<br>Category | Marketing Start<br>Date | Marketing End<br>Date |  |
| OTC monograph final   | part341                 | 04/11/2016            |  |

# Part 2 of 2

# **CAREONE DAYTIME COLD AND FLU**

acetaminophen, dextromethorphan hbr, phenylephrine hcl solution

| Product Information     |               |  |
|-------------------------|---------------|--|
| Item Code (Source)      | NDC:41520-032 |  |
| Route of Administration | ORAL          |  |

| Active Ingredient/Active Moiety  |                                  |                    |  |
|--|----------------------------------|--------------------|--|
| Ingredient Name  | <b>Basis of Strength</b>         | Strength           |  |
| ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)                           | ACETAMINOPHEN                    | 325 mg<br>in 15 mL |  |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN<br>HYDROBROMIDE | 10 mg<br>in 15 mL  |  |

| l | PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - | PHENYLEPHRINE  | 5 mg     |
|---|---|----------------|----------|
| ı | UNII: 1 WS 2 9 7 W6 MV)   | HYDROCHI ORIDE | 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, UNSPECIFIED FORM (UNII: 3980JIH2SW) |          |  |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)              |          |  |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                              |          |  |
| WATER (UNII: 059QF0KO0R)   |          |  |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY)                              |          |  |
| SUCROSE (UNII: C151H8M554)                                       |          |  |
| XANTHAN GUM (UNII: TTV12P4NEE)                                   |          |  |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)                     |          |  |

| Product Characteristics |                      |              |
|-------------------------|----------------------|--------------|
| Color                   | ORANGE (clear)       | Score        |
| Shape                   |                      | Size         |
| Flavor                  | MENTHOL (with fruit) | Imprint Code |
| Contains                |                      |              |

| Packaging |                      |   |                         |                       |
|-----------|----------------------|---|-------------------------|-----------------------|
| #         | Item Code            | Package Description                                   | Marketing Start<br>Date | Marketing End<br>Date |
| 1         | NDC:41520-032-<br>40 | 355 mL in 1 BOTTLE; Type 0: Not a Combination Product |                         |                       |

| Marketing Information  |         |                       |  |
|--|---------|-----------------------|--|
| Marketing Application Number or Monograph Marketing Start Category Citation Date |         | Marketing End<br>Date |  |
| OTC monograph final  | part341 | 04/12/2016            |  |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| OTC monograph final   | part341                                     | 11/02/2016              |                       |
|                       |   |                         |                       |