

COLD PLUS HEAD CONGESTION DAY AND NIGHT- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride
TopCo Associates 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.

TCR - 1162 - 2022-1208

COLD + HEAD CONGESTION DAY

Drug Facts

| <i>Active ingredients (in each caplet)</i> | <i>Purpose</i> |
|---|-----------------------------|
| Acetaminophen 325 mg | Pain reliever/fever reducer |
| Dextromethorphan HBr 10 mg | Cough suppressant |
| Phenylephrine HCl 5 mg | Nasal decongestant |

Uses

- for the temporary relief of the following cold symptoms:
 - minor aches and pains
 - headache
 - sore throat
 - nasal congestion
 - cough
 - sinus congestion and pressure
- helps clear nasal passages
- temporarily reduces fever

COLD + HEAD CONGESTION NIGHT

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|---|-----------------------------|
| Acetaminophen 325 mg | Pain reliever/fever reducer |
| Chlorpheniramine maleate 2 mg | Antihistamine |
| Dextromethorphan HBr 10 mg | Cough suppressant |
| Phenylephrine HCl 5 mg | Nasal decongestant |

Uses

- for the temporary relief of the following cold symptoms:
 - minor aches and pains
 - headache
 - sore throat
 - nasal congestion
 - runny nose and sneezing
 - cough
 - sinus congestion and pressure
- helps clear nasal passages
- relieves cough to help you sleep
- temporarily reduces fever

Warnings

Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. 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
- heart disease

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

Ask a doctor or pharmacist before use if you are

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

When using this product

- **do not exceed recommended dosage**

In addition, when using Cold + Head Congestion Night:

- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, 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

- do not take more than directed (see overdose warning)
- do not take Day and Night caplets at the same time
- do not take more than a total of 10 caplets in 24 hours

adults and | ▪ take 2 caplets every 4 hours

| | |
|----------------------------|---|
| children 12 years and over | ▪ swallow whole – do not crush, chew, or dissolve |
| children under 12 years | ▪ ask a doctor |

Other information

- store between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information and warnings

Inactive ingredients

Cold + Head Congestion Day

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, crospovidone, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

Cold + Head Congestion Night

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

PRINCIPAL DISPLAY PANEL

NDC 36800-927-02

For Adults

TopCare® Health

Cold + Head Congestion Day +Night

Pharmacists Recommend

Daytime

Pain Reliever/Fever Reducer - Acetaminophen

Cough Suppressant – Dextromethorphan HBr

Nasal Decongestant - Phenylephrine HCl

Day Caplet Relieves:

Headache + Body Aches

Fever + Sore Throat

Cough

Nasal Congestion

12 Cool Taste Caplets

Nighttime

Pain Reliever/Fever Reducer - Acetaminophen

Cough Suppressant - Dextromethorphan HBr

Nasal Decongestant - Phenylephrine HCl

Antihistamine* - Chlorpheniramine Maleate*

Night Caplet Relieves:

Headache + Body Aches

Fever + Sore Throat

Cough

Nasal Congestion

Runny Nose*

*Antihistamine in Nighttime Only

8 Cool Taste Caplets

LIFT PANEL FOR MORE DRUG FACTS INFORMATION

| | |
|---|---|
| Warnings Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. 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 ■ 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. | |
| Drug Facts Active ingredients (in each Night caplet) Acetaminophen 325 mg...Pain reliever/fever reducer Chlorpheniramine maleate 2 mg.....Antihistamine Dextromethorphan HBr 10 mg.....Cough suppressant Phenylephrine HCl 5 mg.....Nasal decongestant | Drug Facts Active ingredients (in each Day caplet) Acetaminophen 325 mg...Pain reliever/fever reducer Dextromethorphan HBr 10 mg.....Cough suppressant Phenylephrine HCl 5 mg.....Nasal decongestant |
| Uses ■ for the temporary relief of the following cold symptoms: ■ minor aches and pains ■ headache ■ sore throat ■ runny nose and sneezing ■ cough ■ sinus congestion and pressure ■ helps clear nasal passages ■ temporarily reduces fever | Uses ■ for the temporary relief of the following cold symptoms: ■ minor aches and pains ■ headache ■ sore throat ■ nasal congestion ■ cough ■ sinus congestion and pressure ■ helps clear nasal passages ■ temporarily reduces fever |

DO NOT TAKE THE DAY AND NIGHT CAPLETS AT THE SAME TIME.
Do not take more than a total of 10 caplets in a 24-hour period. Take only as directed.

COLD + HEAD CONGESTION NIGHT **COLD + HEAD CONGESTION DAY**

TopCare health For Adults **Cold + Head**

Cold + Head Congestion Day + Night

+TopCare[®]
health

NDC 36800-927-02

For Adults

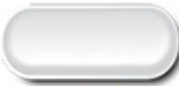
Cold + Head Congestion Day + Night

DAYTIME

PAIN RELIEVER/FEVER REDUCER -
ACETAMINOPHEN
COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr
NASAL DECONGESTANT - PHENYLEPHRINE HCl

DAY CAPLET RELIEVES:

- Headache + Body Aches
- Fever + Sore Throat
- Cough
- Nasal Congestion



actual size

NIGHTTIME

PAIN RELIEVER/FEVER REDUCER -
ACETAMINOPHEN
COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr
NASAL DECONGESTANT - PHENYLEPHRINE HCl
ANTIHISTAMINE* - CHLORPHENIRAMINE MALEATE*

NIGHT CAPLET RELIEVES:

- Headache + Body Aches
- Fever + Sore Throat
- Cough
- Nasal Congestion
- Runny Nose*



actual size

*Antihistamine in
Nighttime Only

**12 COOL TASTE
CAPLETS**

**8 COOL TASTE
CAPLETS**

Drug Facts (continued)
Cold + Head Congestion Night acesulfame potassium, colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone, FD&C blue #1 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

Drug Facts (continued)
Cold + Head Congestion Day acesulfame potassium, colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

Directions ■ do not take more than directed (see overdose warning) ■ do not take Day and Night caplets at the same time ■ do not take more than a total of 10 caplets in 24 hours ■ adults and children ■ take 2 caplets every 4 hours ■ 12 years and over ■ swallow whole; do not crush, chew, or dissolve ■ children under 12 years ■ ask a doctor

Other information ■ store between 20-25° C (68-77° F) in a dry place ■ retain carton for complete product information and warnings

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.

If pregnant or breast-feeding, ask a health professional before use.
These could be signs of a serious condition.
■ new symptoms occur
■ fever gets worse or lasts more than 3 days
■ redness or swelling is present
■ pain, head congestion, or cough gets worse or lasts more than 7 days
■ cough comes back or occurs with rash or headache that lasts

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TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007
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QUESTIONS? 1-888-423-0139
topcare@topco.com
www.topcarebrand.com



Scan here for
informatic
call 1-888-42

Drug Facts (continued)

■ 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 ■ diabetes ■ glaucoma
- 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
- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are

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


When using this product ■ do not exceed recommended dosage

In addition, when using Cold + Head Congestion Night


- excitability may occur, especially in children
- marked drowsiness may occur ■ alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks ■ be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if ■ nervousness, dizziness, or sleeplessness occur

■ Note: Alcohol consumption of much more wine or faster more than 7 days



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FT16202TCR_R3

NDC

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

QUALITY GUARANTEED

This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

For more information or 1-800-33-0139

COLD PLUS HEAD CONGESTION DAY AND NIGHT

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride kit

Product Information

| | | | |
|---------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:36800-927 |
|---------------------|----------------|---------------------------|---------------|

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:36800-927-02 | 1 in 1 CARTON | 08/30/2011 | |

Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|--------|------------------|------------------------|
| Part 1 | 1 BLISTER PACK | 12 |
| Part 2 | 1 BLISTER PACK | 8 |

Part 1 of 2

ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE, PHENYLEPHRINE HYDROCHLORIDE

acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet, coated

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 |
|--|----------|
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| CROSPVIDONE (UNII: 2S7830E561) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|-----------------------|---------------------|----------|
| Color | white | Score | no score |
| Shape | OVAL (capsule-shaped) | Size | 17mm |
| Flavor | MINT | Imprint Code | AAA;1138 |
| 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

ACETAMINOPHEN, CHLORPHENIRAMINE MALEATE, DEXTROMETHORPHAN HYDROBROMIDE, PHENYLEPHRINE HYDROCHLORIDE

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet, coated

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 |
| CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U) | CHLORPHENIRAMINE MALEATE | 2 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 |
|--|----------|
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| ALUMINUM OXIDE (UNII: LMI26O6933) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|--------------|-----------------------|--------------|----------|
| Color | blue | Score | no score |
| Shape | OVAL (capsule-shaped) | Size | 17mm |

| | | | | |
|------------------------------|---|--|-----------------------------|---------------------------|
| Flavor | MINT | Imprint Code | AAA;1139 | |
| Contains | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | | 8 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 | 08/30/2011 | | |

Labeler - TopCo Associates LLC (006935977)

Revised: 12/2022

TopCo Associates LLC