

COLD HEAD CONGESTION - acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride tablet, film coated
Physicians Total Care, Inc.

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.

Cold Head Congestion Drug Facts

Active ingredient (in each caplet)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves these common cold symptoms:
- minor aches and pains
- headache
- sore throat
- nasal congestion
- cough
- sinus congestion and pressure
- helps clear nasal passages

Warnings

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

- more than 12 caplets in 24 hours, which is the maximum daily amount
- 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 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.

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 lasts or is chronic such as occurs with smoking, asthma or emphysema
- cough that occurs with too much phlegm (mucus)

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 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.

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 Liver warning)

| | |
|---------------------------------------|--|
| adults and children 12 years and over | <ul style="list-style-type: none">• take 2 caplets every 4 hours• do not take more than 12 caplets in 24 hours• swallow whole – do not crush, chew or dissolve |
| children under 12 years | <ul style="list-style-type: none">• do not use this adult product in children under 12 years of age |

Other information

- store at 20°-25°C (68°-77°F)

Inactive ingredients

acesulfame potassium, carnauba wax, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, starch, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

See New Warnings Information

Compare to active ingredients in Tylenol® Cold Head Congestion Daytime Caplets

Cold

Head Congestion

Pain Reliever, Cough Suppressant, Nasal Decongestant

Contains 3 Medicines:

Headache/Sore Throat – Acetaminophen

Nasal Congestion – Phenylephrine HCl

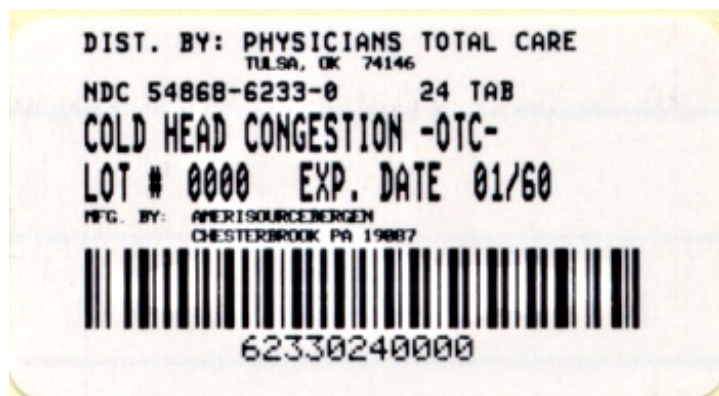
Coughing – Dextromethorphan HBr

Cool Ice® Instant Cooling Sensation

Daytime

Non-Drowsy

NDC 54868-6233-0



Cold Head Congestion Package Label

| COLD HEAD CONGESTION | | | |
|---|----------------|--------------------|-------------------------------|
| acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride tablet, film coated | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:54868-6233(NDC:24385-197) |
| 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) | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A) | |
| POLYVINYL ALCOHOL (UNII: 532B59J990) | |
| POVIDONE (UNII: FZ989GH94E) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|----------|---------|--------------|----------|
| Color | WHITE | Score | no score |
| Shape | CAPSULE | Size | 17mm |
| Flavor | | Imprint Code | L402 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------|----------------------|--------------------|
| 1 | NDC:54868-6233-0 | 2 in 1 CARTON | | |
| 1 | | 12 in 1 BLISTER PACK | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 02/16/2011 | |

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|---------------------|
| Physicians Total Care, Inc. | | 194123980 | relabel |

