

COLD AND HEAD CONGESTION SEVERE- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated
TopCo Associates LLC

TCR - 1175 - 2019-1016

Drug Facts

| <i>Active ingredients (in each caplet)</i> | <i>Purpose</i> |
|---|-----------------------------|
| Acetaminophen 325 mg | Pain reliever/fever reducer |
| Guaifenesin 200 mg | Expectorant |
| 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
 - sinus congestion and pressure
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- 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, chronic bronchitis, 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 exceed recommended dosage

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)**

| | |
|---------------------------------------|---|
| adults and children 12 years and over | <ul style="list-style-type: none">▪ take 2 caplets every 4 hours▪ swallow whole - do not crush, chew, or dissolve▪ do not take more than 10 caplets in 24 hours |
| children under 12 years | <ul style="list-style-type: none">▪ ask a doctor |

Other information

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

Inactive ingredients

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

PRINCIPAL DISPLAY PANEL

NDC 36800-575-02

TopCare® Health

Compare to Tylenol® Cold + Head Congestion Severe Active Ingredients†

Cold + Head Congestion Severe

SEVERE

Acetaminophen, Phenylephrine, Guafenesin

Pain Reliever/Fever Reducer, Nasal Decongestant, Expectorant

Relief of:

- Headache + Body Aches
- Fever + Sore Throat
- Nasal Congestion
- Mucus + Chest Congestion

For Adults

24 COOL TASTE CAPLETS

actual size



COLD AND HEAD CONGESTION SEVERE

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:36800-575 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 200 mg |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ACESULFAME POTASSIUM (UNII: 230V73Q5G9) | |

| |
|--|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) |
| CROSPVIDONE (UNII: 2S7830E561) |
| MAGNESIUM STEARATE (UNII: 70097M6I30) |
| MALTODEXTRIN (UNII: 7CVR7L4A2D) |
| 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 | Size | 19mm |
| Flavor | MINT | Imprint Code | AAA;1119 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:36800-575-02 | 2 in 1 CARTON | 06/30/2017 | |
| 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 Drug | M012 | 06/30/2017 | |

Labeler - TopCo Associates LLC (006935977)