

TOPCARE FLU AND SEVERE COLD AND COUGH- acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride powder, for solution

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.

Topco Associates LLC. Flu & Severe Cold & Cough Drug Facts

Active ingredients (in each packet)

Acetaminophen 650 mg

Diphenhydramine HCl 25 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer

Antihistamine/cough suppressant

Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold:
- minor aches and pains
- minor sore throat pain
- headache
- nasal and sinus congestion
- runny nose
- sneezing
- itchy nose or throat
- itchy, watery eyes due to hay fever
- cough due to minor throat and bronchial irritation
- temporarily reduces fever

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

- in a child under 12 years of age
- if you have ever had an allergic reaction to this product or any of its ingredients
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other product containing diphenhydramine, even one used on skin
- 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
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are

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

When using this product

- **do not exceed recommended dosage**
- avoid alcoholic drinks
- marked drowsiness may occur

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

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- redness or swelling is present
- fever gets worse or lasts more than 3 days
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- 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). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not use more than directed (see overdose warning)**
- take every 4 hours, while symptoms persist. Do not take more than 5 packets in 24 hours unless directed by a doctor.

| Age | Dose |
|--|------------|
| adults and children 12 years of age and over | one packet |
| children under 12 years of age | do not use |

- dissolve contents of one packet into 8 oz. hot water: sip while hot. Consume entire drink within 10-15 minutes.
- if using a microwave, add contents of one packet to 8 oz. of cool water: stir briskly before and after heating. Do not overheat.

Other information

- **each packet contains:** potassium 10 mg and sodium 25 mg
- **phenylketonurics:** contains phenylalanine 13 mg per packet
- store at 20-25°C (68-77°F). Protect product from heat and moisture.

Inactive ingredients

acesulfame potassium, anhydrous citric acid, aspartame, colloidal silicon dioxide, D&C

yellow #10, FD&C blue #1, FD&C red #40, flavors, maltodextrin, pregelatinized starch, sodium citrate, sucrose, tribasic calcium phosphate

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

TopCare® health

NIGHTTIME

COMPARE TO THERAFLU® NIGHTTIME SEVERE COLD & COUGH ACTIVE INGREDIENTS

Flu & Severe Cold & Cough

PAIN RELIEVER – FEVER REDUCER (ACETAMINOPHEN)

ANTIHISTAMINE / COUGH SUPPRESSANT (DIPHENHYDRAMINE HCl)

NASAL DECONGESTANT (PHENYLEPHRINE HCl)

MULTI-SYMP TOM

FOR RELIEF OF:

- Nasal Congestion
- Sore Throat Pain
- Cough
- Runny Nose
- Sneezing
- Body Ache
- Headache
- Fever

6 PACKETS

HONEY LEMON INFUSED WITH WHITE TEA FLAVORS



TOPCARE FLU AND SEVERE COLD AND COUGH

acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride powder, for solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:36800-964 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 650 mg |
| DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 25 mg |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 10 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ACESULFAME POTASSIUM (UNII: 230V73Q5G9) | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| ASPARTAME (UNII: Z0H242BBR1) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| MALTODEXTRIN (UNII: 7CVR7L4A2D) | |
| SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) | |
| SUCROSE (UNII: C151H8M554) | |
| TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28) | |

Product Characteristics

| | | | |
|----------|--|--------------|--|
| Color | WHITE (mixture of white, light yellow-orange particles) , ORANGE | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:36800-964-91 | 6 in 1 CARTON; Type 0: Not a Combination Product | 09/10/2012 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 09/10/2012 | |

Labeler - Topco Associates LLC (006935977)

Revised: 10/2022

Topco Associates LLC