

DAYTIME SEVERE COLD AND FLU RELIEF- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl capsule, liquid filled
CVS Pharmacy

CVS Daytime Severe Cold and Flu Relief

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

- ■ temporarily relieves common cold/flu symptoms: ■ nasal congestion ■ sinus congestion & pressure ■ cough due to minor throat & bronchial irritation ■ minor aches & pains ■ headache ■ fever ■ sore throat ■ reduces swelling of nasal passages ■ temporarily restores freer breathing through the nose ■ promotes nasal and/or sinus drainage ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

Warnings

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

- more than 8 softgels in 24 hours, which is the maximum daily amount for this product
- 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.

Ask a doctor before use if you have

- liver disease
- diabetes
- heart disease
- thyroid disease
- high blood pressure
- 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)

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.

Overdose warning: Taking more than the recommended dose can cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. 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
- do not exceed 8 softgels per 24 hours

| | |
|--------------------------------------|--|
| adults & children 12 years & over | 2 softgels with water every 4 hours |
| children 4 to under 12 years | ask a doctor |
| children under 4 years | do not use |

- when using other Nighttime or Daytime products,
carefully read each label to ensure correct dosing

Other information

- ■ store at room temperature

Inactive ingredients

FD&C Yellow # 6, gelatin, glycerin, polyethylene glycol,
povidone, propylene glycol, purified water, sorbitol
sorbitan , titanium dioxide

Questions or comments? 1-888-333-9792

Principal Display Panel



DAYTIME SEVERE COLD AND FLU RELIEF

acetaminohpen, dextromethorphan hbr, guaifenesin, phenylephrine hcl capsule, liquid filled

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51316-101 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------------|----------|
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 200 mg |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg |
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| GELATIN (UNII: 2G86QN327L) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |

| | | | | |
|--|-------------------------|---|----------------------|--------------------|
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | | | | |
| POVIDONE (UNII: FZ989GH94E) | | | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| SORBITAN (UNII: 6O92ICV9RU) | | | | |
| SORBITOL (UNII: 506T60A25R) | | | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | | | |
| | | | | |
| Product Characteristics | | | | |
| Color | orange (Light Orange) | | Score | no score |
| Shape | CAPSULE (oblong shaped) | | Size | 20mm |
| Flavor | | | Imprint Code | 341;A13 |
| Contains | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:51316-101-24 | 2 in 1 CARTON | 11/10/2022 | |
| 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 | 11/10/2022 | |

Labeler - CVS Pharmacy (062312574)

Revised: 12/2023

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