BASIC CARE DAYTIME SEVERE COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride tablet, film coated Amazon.com Services 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.

Amazon Daytime Severe Cold & Flu Drug Facts

Active ingredients (in each caplet)

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 and pressure
- cough due to minor throat and bronchial irritation
- minor aches and 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 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
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

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: 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

- take only as directed see overdose warning
- do not exceed 8 caplets per 24 hrs

| adults & children 12 yrs & over | 2 caplets with water every 4 hrs |
|---------------------------------|----------------------------------|
| children 4 to under 12 yrs | ask a doctor |
| children under 4 yrs | do not use |

Other information

- each caplet contains: sodium 3 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

croscarmellose sodium, crospovidone, FD&C yellow #6 aluminum lake, flavor, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, silicon dioxide, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Daytime Relief

Compare to Vicks[®] DayQuil[®] Severe + VapoCOOL[™]

active ingredients

Non-Drowsy

Daytime Severe Cold & Flu

Acetaminophen, Phenylephrine HC1, Dextromethorphan HBr, Guaifenesin

actual size

Pain Reliever/Fever Reducer, Nasal Decongestant

Cough Suppressant, Expectorant

Max Strength

24 CAPLETS

Drug Facts (continued) Directions

■ take only as directed - see overdose warning: ■ do not exceed 8 caplets per 24 hrs

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amazon

basic@care

Daytime Relief

NDC 72288-357-62

Non-Drowsy

aytime Severe Cold & Flu

Acetaminophen, Phenylephrine HCI,

Pain Reliever/Fever Reducer, Nasal Decongestant Cough Suppressant, Expectorant

Max Strength

24 CAPLETS



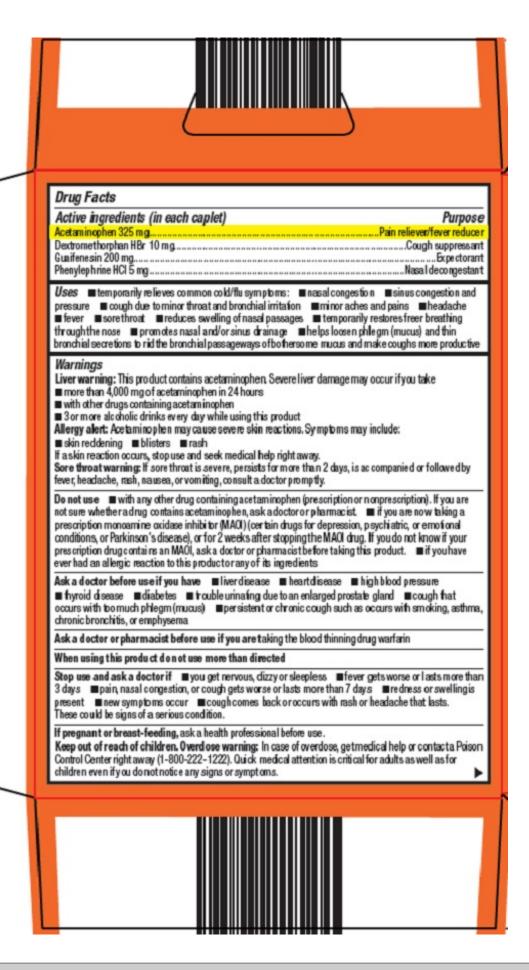
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SEATTLE, WA 98109

Compare to Vicks[®] DayQuil[®] Severe+ VapoCOOL™ active ingredients*



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BASIC CARE DAYTIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride tablet, film coated

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72288-357 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | |
|--|----------------------------------|----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D) | ACETAMINOPHEN | 325 mg | |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg | |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 200 mg | |
| PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6 MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg | |

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48) | |
| CROSPO VIDO NE (15 MPA.S AT 5%) (UNII: 68401960 MK) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| MALTO DEXTRIN (UNII: 7CVR7L4A2D) | |
| MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) | |
| PO VIDO NE, UNSPECIFIED (UNII: FZ989GH94E) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) | |

| Product Characteristics | | | |
|-------------------------|--------|--------------|----------|
| Color | ORANGE | Score | no score |
| Shape | OVAL | Size | 19 mm |
| Flavor | | Imprint Code | L35C |
| Contains | | | |

| I | Packaging | | | |
|---|------------------|---|-----------------------------|---------------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:72288-357-62 | 12 in 1 CARTON | 12/10/2020 | |
| 1 | | $2\ \text{in}\ 1\ \text{BLISTER}$ 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 | 12/10/2020 | |
| | | | |

Labeler - Amazon.com Services LLC (128990418)

Revised: 12/2020 Amazon.com Services LLC