## SIGNATURE CARE NON DROWSY DAYTIME SEVERE COLD AND FLU RELIEFacetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution Safeway

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.

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# Better Living Brands LLC Non-Drowsy Daytime Severe Cold & Flu Relief Drug Facts

### Active ingredients (in each 15 mL)

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:

- sinus congestion and pressure
- nasal congestion
- minor aches and pains
- headache
- sore throat
- fever
- cough due to minor throat and bronchial irritation
- reduces swelling of nasal passages
- promotes nasal and/or sinus drainage
- temporarily restores freer breathing through the nose
- 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

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 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
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to an enlarged prostate gland
- 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 5 days (children) or 7 days (adults)
- 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
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

| adults & children 12 yrs & over | 30 mL every 4 hrs |
|---------------------------------|-------------------|
| children 6 to under 12 yrs      | 15 mL every 4 hrs |
| children 4 to under 6 yrs       | ask a doctor      |
| children under 4 yrs            | do not use        |

#### Other information

- each 15 mL contains: sodium 6 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

# **Inactive ingredients**

butylated hydroxyanisole, edetate disodium, FD&C yellow #6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum

## **Questions?**

1-800-719-9260

# Package/Label Principal Display Panel

Signature care®

**Quality Guaranteed** 

Compare to Vicks® DayQuil® Severe active ingredients

Maximum Strength

Non-Drowsy

Daytime Severe

Cold & Flu Relief

ACETAMINOPHEN 325 mg

Pain Reliever, Fever Reducer

DEXTROMETHORPHAN HBr 10 mg

Cough Suppressant

GUAIFENESIN 200 mg

Expectorant

PHENYLEPHRINE HCl 5 mg

Nasal Decongestant

**ORIGINAL FLAVOR** 

ALCOHOL FREE

12 FL OZ (355 mL)



Quality Guaranteed

NDC 21130-091-40

Compare to Vicks® DayQuil® Severe active ingredients\*

# Maximum Strength

Non-Drowsy Daytime Severe Cold & Flu Relief

**ACETAMINOPHEN** 325 mg

Pain Reliever, Fever Reducer **DEXTROMETHORPHAN HBr 10 mg** 

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# **ORIGINAL** FLAVOR

ALCOHOL FREE

(355 mL)



: 60340 LJ F4

# DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

Scan here for more information P.O. BOX 99, PLEASANTON, CA 94566-0 P.O. BOX 99, PLEASANTON, CA 94566-0009 1-888-723-3929/www.betterlivingbrandsLLC.com



## ARENTS: Learn about teen medicine abuse

www.StopMedicineAbuse.org

Purpose

# Drug Facts

Acetaminophen

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Pain reliever/ 325 mg.....fever reducer
Dextromethorphan HBr

10 mg......Cough suppressant Guaifenesin 200 mg.....Expectorant Phenylephrine HCI 5 mg.....Nasal decongestant

Uses temporarily relieves common cold/flu symptoms: sinus congestion and pressure

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■ minor aches and pains ■ headache ■ sore throat

■ fever ■ cough due to minor throat and bronchial irritation reduces swelling of

nasal passages promotes nasal and/or sinus drainage

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PEEL BACK AT CORNER FOR MORE INFORMATION

: 60340 LJ Bl





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**WO COATING • NO VARNISH** 

- thyroid disease
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- cough that occurs with too much phlegm (mucus)
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Drug Facts (continued)

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Questions? 1-800-719-9260

\*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® DayQuil® Severe.
OUR PROMISE QUALITY & SATISFACTION 100%
GUARANTEED OR YOUR MONEY BACK.

# SIGNATURE CARE NON DROWSY DAYTIME SEVERE COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

#### **Product Information**

| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:21130-091 |
|-------------------------|----------------|--------------------|---------------|
| Route of Administration | ORAL           |                    |               |

| Active Ingredient/Active Moiety  |                                  |                    |  |
|--|----------------------------------|--------------------|--|
| Ingredient Name  | Basis of Strength                | Strength           |  |
| ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)                           | ACETAMINOPHEN                    | 325 mg<br>in 15 mL |  |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN<br>HYDROBROMIDE | 10 mg<br>in 15 mL  |  |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)                               | GUAIFENESIN                      | 200 mg<br>in 15 mL |  |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1W5297W6MV)            | PHENYLEPHRINE<br>HYDROCHLORIDE   | 5 mg<br>in 15 mL   |  |

| Inactive Ingredients   |          |  |  |
|--|----------|--|--|
| Ingredient Name  | Strength |  |  |
| BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)                      |          |  |  |
| EDETATE DISODIUM (UNII: 7FLD91C86K)                              |          |  |  |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8)                             |          |  |  |
| GLYCERIN (UNII: PDC6A3C0OX)                                      |          |  |  |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)                     |          |  |  |
| SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) |          |  |  |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)              |          |  |  |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                              |          |  |  |
| WATER (UNII: 059QF0KO0R)   |          |  |  |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY)                              |          |  |  |
| SUCROSE (UNII: C151H8M554)                                       |          |  |  |
| XANTHAN GUM (UNII: TTV12P4NEE)                                   |          |  |  |

| Product Characteristics |                |              |  |
|-------------------------|----------------|--------------|--|
| Color                   | ORANGE (clear) | Score        |  |
| Shape                   |                | Size         |  |
| Flavor                  | FRUIT, MENTHOL | Imprint Code |  |
| Contains                |                |              |  |

| Packaging |                      |   |                         |                       |
|-----------|----------------------|---|-------------------------|-----------------------|
| #         | Item Code            | Package Description                                   | Marketing Start<br>Date | Marketing End<br>Date |
|           | NDC:21130-091-<br>40 | 355 mL in 1 BOTTLE; Type 0: Not a Combination Product | 01/29/2016              |                       |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| OTC monograph final   | part341                                     | 01/29/2016              |                       |

# **Labeler -** Safeway (009137209)

Revised: 2/2023 Safeway