**SIGNATURE CARE NIGHTTIME SEVERE COLD AND FLU RELIEF- acetaminophen, dextromethorphan hbr, doxylamine succinate, 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 Nighttime Severe Cold & Flu Relief Drug Facts**

**Active ingredients (in each 30 mL)**

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Doxylamine succinate 12.5 mg

Phenylephrine HCl 10 mg

**Purpose**

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

**Uses**

temporarily relieves common cold/flu symptoms:

- sinus congestion and pressure
- nasal congestion
- minor aches and pains
- headache
- runny nose and sneezing
- sore throat
- cough to help you sleep
- 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

**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
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- a sodium-restricted diet

**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 use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

**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
- 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 4 to under 12 yrs | ask a doctor |
| children under 4 yrs | do not use |

**Other information**

- **each 30 mL contains:** sodium 41 mg
- store at 20-25°C (68-77°F)

**Inactive ingredients**

anhydrous citric acid, edetate disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution, sucralose, xanthan gum

**Questions?**

**1-800-719-9260**

**Package/Label Principal Display Panel**

Signature care®

Quality Guaranteed

Compare to Vicks® NyQuil® Severe Cold & Flu active ingredients

Maximum Strength

Nighttime Severe Cold & Flu Relief

ACETAMINOPHEN 650 mg

Pain Reliever, Fever Reducer

DEXTROMETHORPHAN HBr 20 mg

Cough Suppressant

DOXYLAMINE SUCCINATE 12.5 mg

Antihistamine

PHENYLEPHRINE HCl 10 mg

Nasal Decongestant

BERRY FLAVOR

12 FL OZ (355 mL)

Signature care®

Quality Guaranteed

NDC 21130-129-40

**Compare to Vicks® NyQuil® Severe Cold & Flu** active ingredients*

Maximum Strength

# Nighttime Severe Cold & Flu Relief

**ACETAMINOPHEN** 650 mg
Pain Reliever, Fever Reducer

DEXTROMETHORPHAN HBr 20 mg
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PHENYLEPHRINE HCl 10 mg
Nasal Decongestant

BERRY FLAVOR

12 FL OZ
(355 mL)

Empty & Replace Cap

PLASTIC BOTTLE | PLASTIC CUP

how2recycle.info

: 76340 LJ F4

**DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING**

DISTRIBUTED BY: BETTER LIVING BRANDS LLC
P.O. BOX 99, PLEASANTON, CA 94566-0009
1-888-723-3929/www.betterlivingbrandsLLC.com

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## Drug Facts

| Active ingredients (in each 30 mL) | Purpose |
|---|---|
| Acetaminophen 650 mg | Pain reliever/ fever reducer |
| Dextromethorphan HBr 20 mg | Cough suppressant |
| Doxylamine succinate 12.5 mg | Antihistamine |
| Phenylephrine HCl 10 mg | Nasal decongestant |

***Uses*** temporarily relieves common cold/flu symptoms: ■ sinus congestion and pressure ■ nasal congestion ■ minor aches and pains ■ headache ■ runny nose and sneezing ■ sore throat ■ cough to help you sleep ■ 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

***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.

**PEEL BACK AT CORNER FOR MORE INFORMATION**

: 76340 LJ B1

ADHESIVE AREA • NO VARNISH • NO TYPE

## Drug Facts (continued)

**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

## Drug Facts (continued)

**When using this product** ■ do not use more than directed ■ excitability may occur, especially in children ■ marked drowsiness may occur ■ avoid alcoholic drinks ■ be careful when driving a motor vehicle or operating machinery ■ alcohol, sedatives, and tranquilizers may increase drowsiness

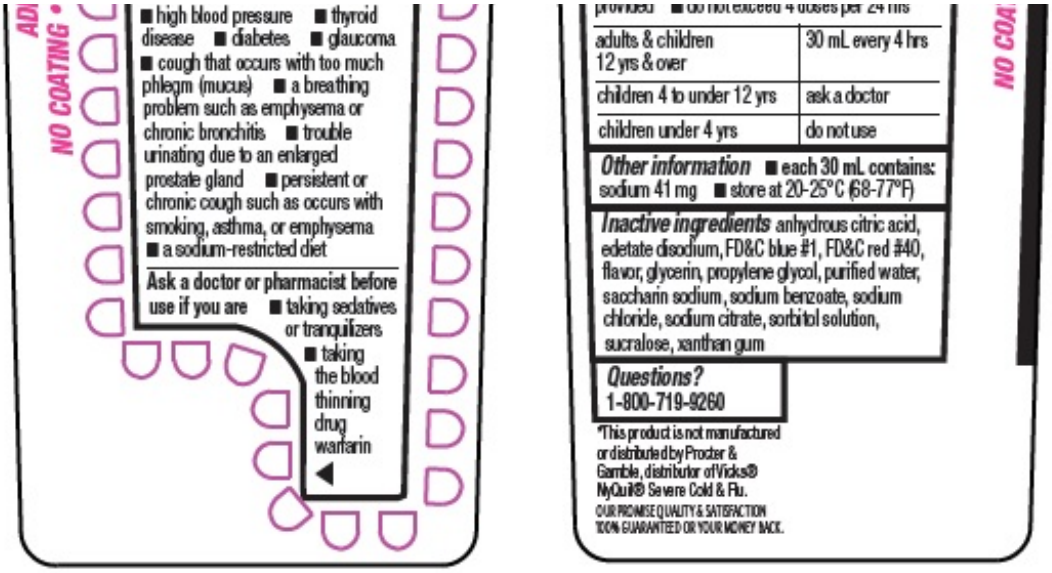
**Stop use and ask a doctor if** ■ you get nervous, dizzy or sleepless ■ pain, nasal congestion, or cough gets worse or lasts more than 7 days ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ new symptoms occur ■ cough comes back or occurs with rash or headache that lasts. 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 ■ only use the dose cup provided ■ do not exceed 4 doses per 24 hrs

ADHESIVE AREA • NO VARNISH • NO TYPE




# SIGNATURE CARE NIGHTTIME SEVERE COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl solution

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:21130-129 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 650 mg in 30 mL |
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 20 mg in 30 mL |
| **DOXYLAMINE SUCCINATE** (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) | DOXYLAMINE SUCCINATE | 12.5 mg in 30 mL |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 10 mg in 30 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **ANHYDROUS CITRIC ACID** (UNII: XF417D3PSL) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SACCHARIN SODIUM** (UNII: SB8ZUX40TY) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **SODIUM CHLORIDE** (UNII: 451W47IQ8X) | |

| | |
|---|---|
| **SODIUM CITRATE** (UNII: 1Q73Q2JULR) | |
| **SORBITOL** (UNII: 506T60A25R) | |
| **SUCRALOSE** (UNII: 96K6UQ3ZD4) | |
| **XANTHAN GUM** (UNII: TTV12P4NEE) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | RED (clear, dark) | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | BERRY | **Imprint Code** | |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:21130-129-40 | 355 mL in 1 BOTTLE; Type 0: Not a Combination Product | 01/24/2016 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part341 | 01/24/2016 | |

## Labeler - Safeway (009137209)

Revised: 2/2023 Safeway