SIGNATURE CARE DAYTIME SEVERE COLD AND FLU RELIEF- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride 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.

Better living Brands LLC Daytime Severe Cold & Flu Relief Drug Facts

Active ingredients (in each 30 mL)

Acetaminophen 650 mg
Dextromethorphan HBr 20 mg
Guaifenesin 400 mg
Phenylephrine HCl 10 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 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 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
- a sodium-restricted diet

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
- 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). Do not refrigerate.

Inactive ingredients

alcohol, anhydrous citric acid, D&C yellow #10, edetate disodium, FD&C blue #1, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution, sucralose

Questions?

1-800-719-9260

Package/Label Principal Display Panel

Signature care $_{\mathbb{R}}$

Quality Guaranteed

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

Maximum Strength

Non-Drowsy

Daytime Severe Cold & Flu Relief

ACETAMINOPHEN 650 mg

Pain Reliever, Fever Reducer

PHENYLEPHRINE HCl 10 mg

Nasal Decongestant

DEXTROMETHORPHAN HBr 20 mg

Cough Suppressant

GUAIFENESIN 400 mg

Expectorant

Vapor Ice®

ALCOHOL 10%

12 FL OZ (355 mL)



Quality Guaranteed

NDC 21130-811-40

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

Maximum Strength

Non-Drowsy Daytime Severe Cold & Flu Relief

ACETAMINOPHEN 650 mg Pain Reliever, Fever Reducer PHENYLEPHRINE HCl 10 mg Nasal Decongestant DEXTROMETHORPHAN HBr 20 mg Cough Suppressant **GUAIFENESIN 400 mg** Expectorant

Vapor Ice®

ALCOHOL 10%



PLASTIC

BOTTLE CUP

: 94M40 LJ F2

Drug Facts

(continued)

Sore throat warning: If sore throat

is accompanied or followed by fever,

headache, rash, nausea, or vomiting,

Do not use with any other drug

containing acetaminophen (prescription

consult a doctor promptly.

is severe, persists for more than 2 days,

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PARENTS: Learn about teen medicine abuse

www.StopMedicineAbuse.org

S 1872 RD 22063

Purpose

fever reducer

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Uses temporarily relieves common cold/flu symptoms: sinus congestion and pressure ■ nasal congestion ■ minor aches and pains ■ headache ■ sore throat

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■ skin reddening ■ blisters ■ rash

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PEEL BACK AT CORNER FOR MORE INFORMATION

: 94M4O LJ Bl

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adults & children 30 mL every 4 hrs 12 vrs & over children A to under 12 ws

VARNISH . NO TYPE

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• NO TYPE NO WARMSH





SIGNATURE CARE DAYTIME SEVERE COLD AND FLU RELIEF

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-811
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL (UNII: 3K9958V90M)		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		

SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:21130-811- 40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/04/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/04/2020	

Labeler - Safeway (009137209)

Revised: 2/2023 Safeway