FAMILY DOLLARSEVERE NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and phenylephrine hydrochloride solution
FAMILY DOLLAR SERVICES INC

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.

Severe NightTime 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

Pain reliever/fever reducer
Cough suppressant
Antihistamine
Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

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

Warnings

Liver warning

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

- more than 4 doses 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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to enlarged prostate gland
- 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.

In case of overdose, get medical help or contact a Poison Control Center right away at 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
- 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 years	do not use

Other information

- **each 30 mL contains:** sodium 77 mg
- Store at room temperature.
- Do not refrigerate.

Inactive ingredients

Anhydrous citric acid, disodium edetate, FD&C Red No. 40, FD&C Blue No. 1, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sodium chloride, sodium citrate dihydrate, sorbitol, sucralose, xanthan gum.

Questions?

1-866-467-2748

Distributed by:

PRINCIPAL DISPLAY PANEL - 354mL Bottle Label

*Compare to the active ingredients inVICKS® NyQuil™ Severe Cold & Flu

NDC 55319-681-08

Severe

NightTime
Cold & Flu

Relief

Acetaminophen- Pain reliever/Fever reducer

Phenylephrine HCl – Nasal decongestant

Doxylamine Succinate - Antihistamine

Dextromethorphan HBr – Cough suppressant

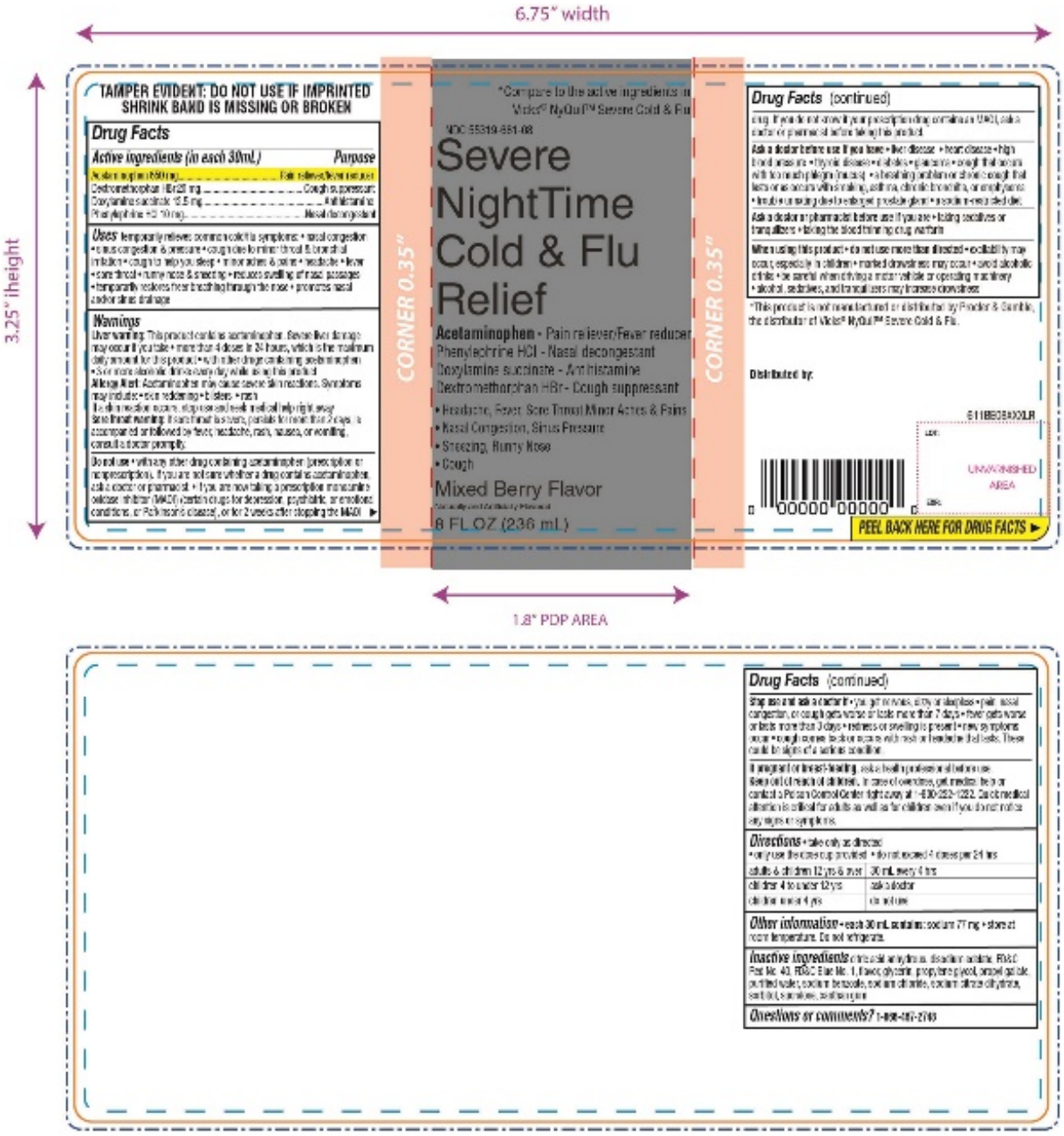
- Headache, Fever, Sore Throat,

  Minor Aches & Pains
- Nasal Congestion & Sinus Pressure
- Sneezing, Runny Nose
- Cough

Mixed Berry Flavor

Naturally and Artificially Flavored

8 FL OZ (236 ml)



FAMILY DOLLARSEVERE NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and phenylephrine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55319-681
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	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 RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	RED	**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-681-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/07/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/07/2023	

Labeler - FAMILY DOLLAR SERVICES INC (024472631)