## GOOD SENSE SEVERE DAYTIME COLD AND FLU- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution L. Perrigo Company

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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#### Perrigo Severe Day Time Cold & Flu 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
- reduces swelling of nasal passages
- sore throat
- promotes nasal and/or sinus drainage
- fever
- cough due to minor throat and bronchial irritation
- 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
- 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
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, nasal congestion, or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- 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 or comments?**

1-800-719-9260

## Package/Label Principal Display Panel

## **GOODSENSE**®

Maximum Strength Relief

Non-Drowsy

Pain Reliever, Fever Reducer

**Nasal Decongestant** 

Cough Suppressant, Expectorant

Severe DayTime Cold & Flu

Acetaminophen

Dextromethorphan HBr

Guaifenesin

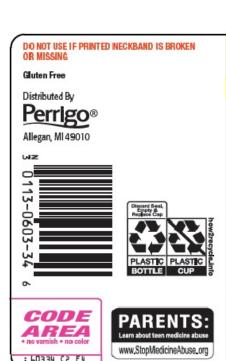
Phenylephrine HCI

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Chest Congestion Cough
- Nasal/Sinus Congestion & Sinus Pressure

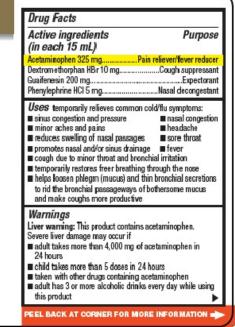
Compare to active ingredients of Vicks® DayQuil® Severe

8 FL OZ (237 mL)

Alcohol Free







ADHESIVE AREA NO COPY

#### Drug Facts (continued)

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■ skin reddening ■ blisters ■ rash

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#### Drug Facts (continued)

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Questions or comments? 1-800-719-9260

#### GOOD SENSE SEVERE DAYTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:0113-0603 Route of Administration ORAL

	Active Ingredient/Active Moiety		
ı	Ingredient Name	<b>Basis of Strength</b>	Strength
	ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg in 15 mL

<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 15 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg 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			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0113-0603- 34	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/19/2013	
2	NDC:0113-0603- 40	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/19/2013	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/19/2013	

## Labeler - L. Perrigo Company (006013346)

Revised: 12/2021 L. Perrigo Company