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

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 HCl

- 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



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								
Ingredient Name		Basis of Stre	ength	Strength				
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)		ACETAMINOPHEN		325 mg in 15 mL				

DEXTROMETHORPHAN H (DEXTROMETHORPHAN - UN	IYDROBROMIDE (UNII: 9D2RTI9KYH) NII:7355X3ROTS)	DEXTROMETHORP HYDROBROMIDE	HAN 10 mg in 15 mL
GUAIFENESIN (UNII: 495W	/7451VQ) (GUAIFENESIN - UNII:495W7451VQ) GUAIFENES IN	200 mg in 15 mL
Phenylephrine Hydro UNII:1WS297W6MV)	CHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPH	RINE - PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL
Inactive Ingredient	IS		
	Ingredient Name		Strength
BUTYLATED HYDROXYAN	NISOLE (UNII: REK4960K2U)		
EDETATE DISODIUM (UNI	II: 7FLD91C86K)		
FD&C YELLOW NO. 6 (UI	NII: H77VEI93A8)		
GLYCERIN (UNII: PDC6A3C	.00X)		
	D FORM (UNII: L7T10EIP3A)		
	ONOBASIC, UNSPECIFIED FORM (UNII: 3	980JIH2SW)	
	, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
PROPYLENE GLYCOL (UN			
WATER (UNII: 059QF0KO0			
SACCHARIN SODIUM (UN	·		
SUCROSE (UNII: C151H8M			
XANTHAN GUM (UNII: TTV	12P4NEE)		
Product Character	istics		
Color	ORANGE (clear)	Score	
Shape		Size	
Flavor	FRUIT, MENTHOL	Imprint Code	
Contains			
Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
	Lie 1 DOTTIE Trace O Natio Combination		
1 NDC:0113-0603- 237 m 34 Produc	L in 1 BOTTLE; Type 0: Not a Combination ct	11/19/2013	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M012	11/19/2013	

Labeler - L. Perrigo Company (006013346)