VICKS SEVERE COLD AND FLU- acetaminophen, chlorpheniramine maleate, and dextromethorphan hydrobromide liquid
Procter & Gamble Manufacturing 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.

Vicks DayQuil Severe Cold & Flu Honey

Drug Facts

Active ingredients (in each 15 mL)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifensin 200 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant

Expectorant

Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- minor aches & pains
- headache
- fever
- sore throat
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions torid 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 doses (30 mL each) in 24 hours, which is the maximum daily amount for this product
- child takes more than 4 doses (15 mL each) in 24 hours, which is the maximum daily amount for this product

- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks daily 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 is 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
- trouble urinating due to enlarged prostate gland
- 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

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 5 days (children) 7 days (adults)
- 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. Quick medical attention is critical for adults & 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 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 14 mg
- Store at no greater than 25C and do not refrigerate.

Inactive ingredients

citric acid, D&C Yellow No. 10, FD&C Green No. 3, FD&C Red No. 40, FD&C Yellow No. 6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

Questions?

1-800-362-1683

Made in Canada

DIST. BY PROCTER & GAMBLE, CINCINNATI, OH 45202

PRINCIPAL DISPLAY PANEL - 354 mL Bottle Label

VICKS®

DayQuil *SEVERE*™

HONEY FLAVOR

COLD & FLU

Acetaminophen,

Guaifensin, Phenylephrine HCl,

Dextromethorphan HBr

Headache, Fever, Sore Throat, Minor Aches & Pains

Chest Congestion,

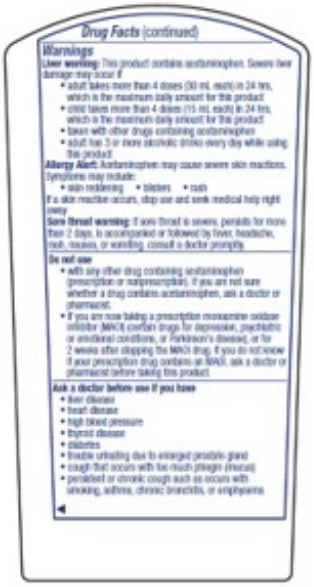
Thins & Loosens Mucus

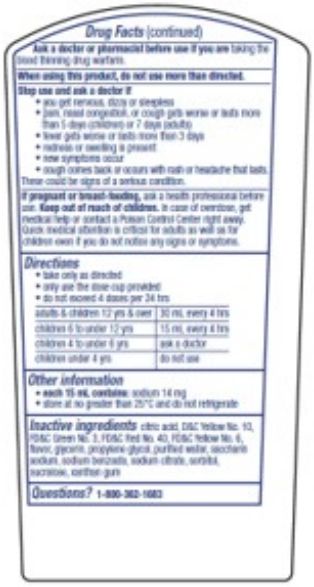
Nasal Congestion, Sinus Pressure

Cough

Non-Drowsy

12 FL OZ (354 ml)





VICKS SEVERE COLD AND FLU

acetaminophen, chlorpheniramine maleate, and dextromethorphan hydrobromide liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37000-970

Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 15 mL

Inactive Ingredients	
Ingredient Name	**Strength**
XANTHAN GUM (UNII: TTV12P4NEE)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SORBITOL (UNII: 506T60A25R)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics			
Color	brown	**Score**	
Shape		**Size**	
Flavor	HONEY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:37000-970-12	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/28/2020	
2	NDC:37000-970-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/28/2020	

Labeler - Procter & Gamble Manufacturing Company (004238200)

Revised: 4/2020 Procter & Gamble Manufacturing Company