

**VICKS FORMULA 44 VAPOCOOL COUGH AND CHEST CONGESTION-
acetaminophen, phenylephrine hydrochloride, dextromethorphan
hydrobromide, and guaifenesin solution
The Procter & Gamble Manufacturing Company**

Vicks ® Formula 44DM VapoCool™ Cough & Chest Congestion

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:
- 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 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 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
- trouble urinating due to 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
- 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.

In case of overdose, get medical help or contact a Poison Control Center right away. 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

children 4 to under 12 yrs

children under 4 yrs

30 mL every 4 hrs

ask a doctor

do not use

Other information

- **each 30 mL dose cup contains:** sodium 81 mg
- store at no greater than 25°C and do not refrigerate

Inactive ingredients

alcohol, citric acid, D&C Yellow No. 10, FD&C Blue No. 1, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol, sucralose

Questions?

1-800-362-1683

TAMPER EVIDENT: Do not use if printed shrinkband is broken or missing.

**DIST. BY PROCTER & GAMBLE,
CINCINNATI OH 45202**

PRINCIPAL DISPLAY PANEL - 236 mL Bottle Label

VICKS®
 FORMULA 44™ DM
 VapoCOOL™
 COUGH & CHEST CONGESTION
Acetaminophen, Guaifenesin, Phenylephrine HCl, Dextromethorphan HBr
 Fever, Minor Aches & Pains
 Chest Congestion, Loosens Mucus
 Nasal Congestion, Sinus Pressure
 Cough

Alcohol 10%
 8 FL OZ (236 mL)



Drug Facts (continued)
Warnings
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take
 • more than 4 doses in 24 hrs, which is the maximum daily amount for this product.
 • taken 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

Drug Facts (continued)
Warnings
 • trouble urinating due to 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
 • 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. In case of overdose, get medical help or contact a Poison Control Center right away. 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 cap 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

Drug Facts (continued)
Other information
 • each 30 mL contains: sodium 81 mg
 • store at no greater than 25°C and do not refrigerate
Inactive ingredients alcohol, citric acid, D&C Yellow No. 10, FD&C Blue No. 1, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol, sucralose
Questions? 1-800-362-1683

VICKS FORMULA 44 VAPOCOOL COUGH AND CHEST CONGESTION

acetaminophen, phenylephrine hydrochloride, dextromethorphan hydrobromide, and guaifenesin solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69423-964
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 30 mL	

DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ALCOHOL (UNII: 3K9958V90M)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor	ANISE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69423-964-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/01/2020	

Labeler - The Procter & Gamble Manufacturing Company (004238200)