EQUATE VAPOR ICE COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride tablet, film coated Wal-Mart Stores 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.

Wal-Mart Vapor Ice[™] Cold & Flu Drug Facts

Active ingredients (in each caplet)

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:
- nasal congestion
- sinus congestion and pressure
- cough due to minor throat and bronchial irritation
- minor aches and 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 4,000 mg of acetaminophen in 24 hours
- 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.
- 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
- 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.

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
- do not exceed 8 caplets per 24 hrs

adults & children 12 yrs & over	2 caplets with water every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- each caplet contains: sodium 3 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

croscarmellose sodium, crospovidone, FD&C yellow #6 aluminum lake, flavor, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, silicon dioxide, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

1-888-287-1915

Package/Label Principal Display Panel

Compare to Vicks $^{\mathbb{R}}$ DayQuil $^{\mathbb{R}}$ Severe+ VapoCOOL $^{^{\text{TM}}}$ active ingredients

NON-DROWSY

DAYTIME SEVERE+ VAPOR ICE[™] Cold & Flu

Acetaminophen – Pain Reliever/Fever Reducer

Phenylephrine HCl - Nasal Decongestant

Dextromethorphan HBr – Cough Suppressant

Guaifenesin – Expectorant

Relief of:

Minor aches & pains, fever

Nasal congestion & sinus pressure

Cough

Chest congestion

Alcohol-Free and Antihistamine-Free

Actual Size

24 CAPLETS



EQUATE VAPOR ICE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-813
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients		
Ingredient Name	Strength	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
CROSPO VIDO NE (15 MPA.S AT 5%) (UNII: 68401960 MK)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
MALTO DEXTRIN (UNII: 7CVR7L4A2D)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)		
PO VIDO NE, UNSPECIFIED (UNII: FZ989GH94E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

Product Characteristics				
Color	ORANGE	Score	no score	
Shape	OVAL	Size	19 mm	
Flavor		Imprint Code	L35C	
Contains				

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:49035-813-62	12 in 1 CARTON	07/16/2020	
l	1	2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/16/2020	

Labeler - Wal-Mart Stores Inc (051957769)

Revised: 7/2020 Wal-Mart Stores Inc