# DAYTIME SEVERE COLD AND FLU MAXIMUM STRENGTH- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated HEB

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.

-----

HEB - 1178 - 2022-0922

## **Drug Facts**

Active ingredients (in each caplet)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

#### Uses

- temporarily relieves common cold/flu symptoms:
  - nasal congestion
  - sinus congestion and pressure
  - cough due to minor throat & 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 8 caplets in 24 hours, which is the maximum daily amount
- 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 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

Taking more than directed can cause serious health problems. 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 4 doses per 24 hours

adults and children 12 years and over	take 2 caplets every 4 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

#### Other information

- store between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information and warnings

## **Inactive ingredients**

colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

### **Questions or comments?**

1-844-705-4384

#### PRINCIPAL DISPLAY PANEL

Compare to Vicks® DayQuil® Severe Cold & Flu Caplets active ingredients† NDC 37808-178-03

H-E-B®

Maximum Strength

Daytime

Severe Cold & Flu

Acetaminophen /Pain Reliever /Fever Reducer

Dextromethorphan HBr / Cough Suppressant

Guaifenesin / Expectorant

Phenylephrine / Nasal Decongestant

Cold & Flu

Headache, Fever, Sore Throat, Minor Aches & Pains

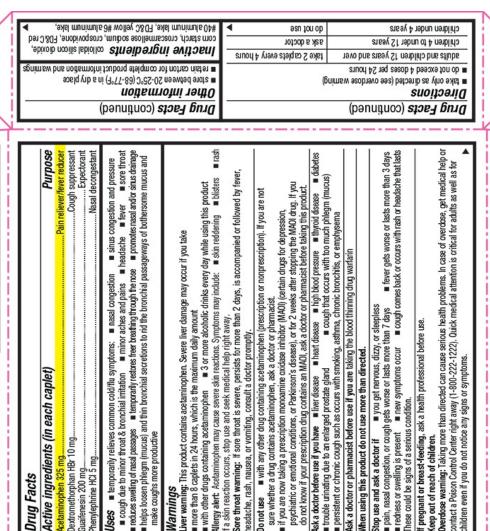
Nasal & Sinus Congestion

Cough

Chest Congestion

24 CAPLETS

actual size



Questions or comments?

Drug Facts (continued)

polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide magnesium stearate, maltodextrin, microcrystalline cellulose

†This product is not manufactured or distributed by Proctor & Gamble, distributor of Vicks® DayQuil® Severe Cold & Flu Caplets

DISTRIBUTED BY H-E-B° SAN ANTONIO, TX 78204

IF BLISTER UNITS ARE

DO NOT USE

Active ingredients (in each caplet)

Orug Facts

Dextromethorphan HBr 10 mg

 promotes nasal and/or sinus drainag helps loosen phiegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and temporarily relieves common cold/flu symptoms:

cough due to minor throat & bronchial irritation reduces swelling of nasal passages make coughs more productive

iver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 8 caplets in 24 hours, which is the maximum daily amoun

llergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters 3 or more alcoholic drinks every day while using this product other drugs containing acetaminophen

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, Do not use with any other drug containing acetaminophen (prescription or nonprescription). If you are not headache, rash, nausea, or vomiting, consult a doctor promptly

sure whether a drug contains acetaminophen, ask a doctor or pharmacis

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) 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 are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression,

 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 Stop use and ask a doctor if wou get nervous, dizzy, or sleepless pain, nasal congestion, or cough gets worse or lasts more than 7 days When using this product do not use more than directed.

Stop use and ask a doctor if

han 7 days = fever gets worse or lasts more than 3 days = cough comes back or occurs with rash or headache that lasts pregnant or breast-feeding, ask a health professional before use new symptoms occur hese could be signs of a serious condition. out of reach of children.

children even if you do not notice any signs or symptoms 34592-2208

contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for

38 4 F117803HEB

(H-E-B)

Phenylephrine HCl 5 mg.

Guaifenesin 200 mg

Maximum Strength

Cold & Flu

Compare to Vicks\* DayQuil\* Severe Cold & Flu Caplets active ingredients





## DAYTIME SEVERE COLD AND FLU MAXIMUM STRENGTH

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

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-178
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients				
Ingredient Name	Strength			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)				
CROSPOVIDONE (UNII: 2S7830E561)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				

ALUMINUM OXIDE (UNII: LMI26O6933)

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)

MAGNESIUM STEARATE (UNII: 70097M6I30)

MALTODEXTRIN (UNII: 7CVR7L4A2D)

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

POLYVINYL ALCOHOL (UNII: 532B59J990)

POVIDONE (UNII: FZ 989GH94E)

STARCH, PREGELATINIZED CORN (UNII: 08232NY3SJ)

STEARIC ACID (UNII: 4ELV7Z 65AP)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics			
Color	orange	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	AAA;1178
Contains			

	Packaging					
	# Item Code Package Description		Marketing Start Date	Marketing End Date		
l	1 NDC:37808- 178-03	2 in 1 CARTON	05/01/2016			
	1	12 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	05/01/2016	

# **Labeler -** HEB (007924756)

Revised: 9/2022 HEB