

SEVERE COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated
Harmon 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.

HAR - 1178 - 2019-1009

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

Inactive ingredients

colloidal silicon dioxide, 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

PRINCIPAL DISPLAY PANEL

CORE VALUES

Compare to the active ingredients in Vicks® DayQuil® Severe Cold + Flu

Maximum Strength

DayTime Severe

Cold & Flu

Acetaminophen, Phenylephrine HCl, Dextromethorphan HBr, Guaifenesin

Pain Reliever / Fever Reducer, Nasal Decongestant, Cough Suppressant, Expectorant

For relief of:

Headache, Fever, Sore Throat, Minor Aches & Pains

Nasal / Sinus Congestion & Sinus Pressure

Cough

Chest Congestion

Actual Size

DAYTIME NON-DROWSY

24 CAPLETS

DO NOT USE IF BLISTER UNITS ARE
TORN OR BROKEN

Drug Facts (continued)
Other Information
■ store between 20-25°C (68-77°F) in a dry place
■ retain carton for complete product information

Drug Facts (continued)
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
ask a doctor
children 4 to under 12 years
children under 4 years do not use

Drug Facts (continued)
Inactive Ingredients colloidal silicon dioxide, croscarmellose sodium, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, methylcellulose, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® DayQuil® Severe Cold & Flu.
Distributed by Liberty Procurement Co. Inc.
650 Liberty Ave.
Union, NJ 07083 USA
Visit us at: www.facevalues.com
SATISFACTION GUARANTEED
Or Your Money Back

Drug Facts
Active ingredients (in each caplet)
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 free 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 redness ■ 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.



Maximum Strength
DayTime SEVERE
Cold & Flu

CORE VALUES™

Compare to active ingredients in Vicks® DayQuil® Severe Cold & Flu*

Maximum Strength
DayTime SEVERE
Cold & Flu

Acetaminophen, Phenylephrine HCl, Dextromethorphan HBr, Guaifenesin
Pain Reliever / Fever Reducer, Nasal Decongestant, Cough Suppressant, Expectorant

NC

NC

Pain Reliever / Fever Reducer, Nasal Decongestant, Cough Suppressant, Expectorant

For relief of:

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Nasal / Sinus Congestion & Sinus Pressure
- Cough
- Chest Congestion



DAYTIME
NON-DROWSY

Actual Size



24 CAPLETS

NC

SEVERE COLD AND FLU

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63940-342
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE, UNSPECIFIED (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, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

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
1	NDC:63940-342-03	2 in 1 CARTON	09/11/2018	07/31/2024
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	09/11/2018	07/31/2024

Labeler - Harmon Stores Inc. (804085293)

Revised: 11/2022

Harmon Stores Inc.