COOLING SEVERE DAYTIME COOLING SEVERE NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, doxylamine succinate CVS Pharmacy

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.

CVS Pharmacy, Inc. Cooling Severe Daytime Cooling Severe Nighttime Drug Facts

Active ingredients (in each caplet) Daytime

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:

- fever
- nasal congestion
- sinus congestion and pressure
- cough due to minor throat and bronchial irritation
- headache
- sore throat
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- minor aches and pains
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- promotes nasal and/or sinus drainage

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

- thyroid disease
- diabetes
- liver disease
- heart disease
- high blood pressure
- 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?

1-800-719-9260

Active ingredients (in each caplet) Nighttime

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion and pressure
- cough due to minor throat and bronchial irritation
- cough to help you sleep
- · minor aches and pains
- headache
- fever
- sore throat
- runny nose and sneezing
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage

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

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- 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
- diabetes
- high blood pressure
- thyroid disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- do not use more than directed
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

alcohol, sedatives, and tranquilizers may increase drowsiness

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

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- · 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

• store at 20-25°C (68-77°F)

Inactive ingredients

crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, FD&C yellow #6 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, silicon dioxide, stearic acid, sucralose, talc, titanium dioxide

Ouestions or comments?

1-800-719-9260

Package/Label Principal Display Panel

CVS Health™

Compare to the active ingredients in Vicks[®] DayQuil[®] Severe+VapoCOOL[™]

Cooling Severe Daytime

COLD & FLU RELIEF

ACETAMINOPHEN - Pain reliever/Fever reducer

PHENYLEPHRINE HCI - Nasal decongestant

DEXTROMETHORPHAN HBr - Cough suppressant

GUAIFENESIN - Expectorant

Relieves:

Minor aches, pains & fever

Nasal congestion & Sinus pressure

Cough

Chest congestion

Actual Size

16 CAPLETS

CVS Health™

Compare to the active ingredients in Vicks[®] NyQuil[®] Severe+VapoCOOL[™]

Cooling Severe Nighttime

COLD & FLU RELIEF

ACETAMINOPHEN - Pain reliever/Fever reducer

PHENYLEPHRINE HCl - Nasal decongestant

DOXYLAMINE SUCCINATE - Antihistamine

DEXTROMETHORPHAN HBr - Cough suppressant

Relieves:

Minor aches, pains & fever

Nasal congestion & Sinus pressure

Sneezing, runny nose

Cough

Actual Size

8 CAPLETS



Compare to the active ingredients in Vicks® DayQuil® Severe+VanoCOOL



Compare to the active ingredients in Vicks® NyQuil® Severe+VapoCOOL* NDC 69842-585-90

Cooling Severe Daytime

Cooling Severe Nighttime

COLD & FLU RELIEF

ACETAMINOPHEN - Pain reliever/Fever reducer PHENYLEPHRINE HCI - Nasal decongestant DEXTROMETHORPHAN HBr - Cough suppressant **GUAIFENESIN** - Expectorant

Relieves:

- Minor aches, pains & fever
- Nasal congestion &
- Cough
- Chest congestion



16 CAPLETS

COLD & FLU RELIEF

ACETAMINOPHEN - Pain reliever/Fever reducer PHENYLEPHRINE HCI - Nasal decongestant DOXYLAMINE SUCCINATE - Antihistamine DEXTROMETHORPHAN HBr - Cough suppressant

Relieves:

- Minor aches, pains & fever
- Nasal congestion & Sinus pressure
- · Sneezing, runny nose
- Cough



8 CAPLETS

Drug Facts Cooling Severe Nightime

Active ingredients (in each captet) Purpos e ...C ough suppres sant Doxylamire succinate 625 mg. RhenylephrineHC15 mg........ .Na saldec onges tant

Uses temporally relieve commons definisy motions: whereast congestion is since congestion and pressure in cough due to minor threat and bronch it in tation in cough to help yous begins in minor actives and parts in headlache in lever in one of those who my more ands nearly in actives seeling of madiginary in minor actives the active of madiginary in the case of the promote seasal and/or since dealing ge

tiver worning: This product contains ace taming then. Severe liver change may occur if you take in more than 4,000 mgo face taming then in 24 hours in with other drugs.

Drug Facts Cooling Severe Dayti

Active ing edients (in each caplet)

Purpos e Depatromet horphan HBr 10 mg....... ... Cough suppres sant Pte nylephrine HC IS mg.....

Uses temporarly neleves common cold'flu symptoms: ■ fever Uses temporary eleves commonced fit symptoms: In lever
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Morey Back Guarantee



#309141

Drug Facts (continued)

containing acetaminophen

3 or more d'orbidic d'hisseeny day while using this product
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4 skin reddening

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manin country morses mass Taskin padini cours, shop use and sek medical help ight away Sone throat werning: Fore himoatis severa persits for more than 2 days, is accompanied or followed by fever, head achar as him uses, or vormiting consult a doctor promptly.

Do not use with any other drug containing aceterning here in those many seems of the property of the property

Ask a doctor before use if you have what disease when disease displaces with pooling his procession of the disease of the consent to be much philipm (muons) with the much philipm (muons) with the consent the present or form or copies has consent the moting, asthma, or emphyse mail to the least of the consent the moting, as the moting as the moting as the consent to the consent the moting as the moting as

Ask a doctor or pharmacist before use if you are takings adatives or tranquilizers in taking the blood thinning drug war farin

and tranquilizers may increase of ow siness.

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If pregnant orbreast-feeding, as ka health professional before use Keepout of rach of drill from Overbose warning: Incase of overdose, get medical hid por contacts Pois on Control Center right away (1-800-222-1222), Oulds medical attention is critical for clude as well as for children even if you do no throthe early signs or symptoms.

Drug Facts (continued)

invermings Liverwaming: This product contains as eterninophen. Se ver e liver damage

live waining: This product contains a starning here Serve i her drange may occur if you take ill more than 4,000 mgot attaining her and on the drange may he other drugs containing actism helphon ill all or more alcohold drinks every day while using this product. Allegy ahert Actaminophen may ocus e severeskin in actions. Symptoms may include: ill askin edicating ill bit lates ill askin edicating in a bit askin actions. Some throat warnings! for the host is serve a per is ble for more than 2 days, is accompanied or followed by fever he ads the, rash, nazes a crowniting, consult added to promptly.

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Whenus ing this product do not use more than directed

Stop use and ask a doctor if ■ youget nervous, dizzy or sleepless mapain, næd congætion, or coughigets wose or lasts more than? deps malever gels wose or læst more fran 3 days mar denes sor swelling t præent man new symptoms cocur mac cough come sback or occurs with rash or headache that hists. The se could be sign so fais ericus condition. 🔻

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Drug Facts (continued)

Directions take only asdirected - see overdose warning

do not exceed & caplets per 24 hrs	
adults & chiden 12 yrs &over	2 captits with water every4 hrs
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chiden urder 4 vrs	do notuse

Other information stop at 20-25° C(68-77°F)

Inactive ingred ents crospovidons D&C yellow#10aluminumlale, FD&Cblue#1 aluminum ble, FIX Chie & aluminum lake, Pl &Cyrd ov #5 duminum lake, flacymagnesium sleasab, microcys bline od lubse, pole thlene glydl, polynny lat drol poel dore, pe gabinisx slach, propiere glycol, silicon doxide, sleat a add, sur dose, talc, thanium dioxide

Questions or comments? 1-800-719-9260

Drug Facts (continued)

If pregnant or beast-beding, aska leath professional before use. Keep act of reach of children. O endose werning: In case of over does, getting bedied the processional control Control right away(1-900-222-1222). Quick medical attention is critical for adults as well as for childrene venify ou do not notice any signs or symptoms.

Directions ■ take only as directed - see overdose warning ■ do not exceed 8c aplets per 24 hrs

aduls &children 12 y s & over	2c aplets with water every 4hrs	
children 4 tounder 12 yrs	askadodor	
children under4 yrs	do not use	

Other inform ation ■ each caplet contains:sedium 3mg ■ store at 20:25°C (68-7° F)

COOLING SEVERE DAYTIME COOLING SEVERE NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, doxylamine succinate kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69842-585

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:69842-585- 90	1 in 1 CARTON; Type 0: Not a Combination Product	12/16/2019	

Quantity of Parts

_	•	
Part #	Package Quantity	Total Product Quantity
Part 1	8 BLISTER PACK	16
Part 2	4 BLISTER PACK	8

Part 1 of 2

COOLING SEVERE DAYTIME

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

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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 In	gredients	
	Ingredient Name	Strength
CROSCARMEL	LOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDO	NE (15 MPA.S AT 5%) (UNII: 68401960MK)	

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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			

Part 2 of 2

COOLING SEVERE NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride tablet, film coated

Prod	uct	Infor	rmation
	uct		HILACIOIL

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

Strength

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients		
Ingredient Name	Strength	
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)		
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics			
Color	GREEN	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	L72V
Contains			

P	Packaging				
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date	
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		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/16/2019	

Labeler - CVS Pharmacy (062312574)

Revised: 12/2022 CVS Pharmacy