BASIC CARE DAYTIME NIGHTTIME SEVERE COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, guaifenes in, phenylephrine hydrochloride

L. Perrigo Company

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.

Amazon Daytime Nighttime Sever Cold & Flu Drug Facts

Active ingredients (in each caplet) - Nighttime

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

Active ingredients (in each caplet) - Daytime

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purpose - Nighttime

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Purpose - Daytime

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses - Nighttime

- 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

Uses - Daytime

- 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 - Nighttime

- 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 before use if you have - Daytime

- 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 - Nighttime

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

Ask a doctor or pharmacist before use if you are - Daytime

taking the blood thinning drug warfarin

When using this product - Nighttime

- 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

When using this product - Daytime do not use more than directed

Stop use and ask a doctor if - Nighttime

- 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.

Stop use and ask a doctor if - Daytime

- 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 – Nighttime and Daytime

- take only as directed see overdose warning
- do not exceed 4 doses 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 - Nighttime

• store at 20-25°C (68-77°F)

Other information - Daytime

- each caplet contains: sodium 4 mg
- store at 20-25°C (68-77°F)

Inactive ingredients - Nighttime

crospovidone, D&C yellow no. 10 aluminum lake, FD&C blue no. 1 aluminum lake, FD&C blue no. 2 aluminum lake, FD&C yellow no. 6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

Inactive ingredients - Daytime

croscarmellose sodium, crospovidone, FD&C blue #2 aluminum lake, FD&C red #40 aluminum lake, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Daytime Relief

Compare to Vicks[®] DayQuil[®] Severe active ingredients

Non-Drowsy

daytime severe cold & flu

Acetaminophen, Phenylephrine HCl, Dextromethorphan HBr, Guaifenesin

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

Alcohol Free/Antihistamine Free

Max Strength

actual size

16 Caplets

Nighttime Relief

Compare to Vicks[®] NyQuil[®] Severe active ingredients

nighttime severe cold & flu

Acetaminophen, Phenylephrine HCl, Doxylamine Succinate, Dextromethorphan HBr

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

Alcohol Free

Max Strength

actual size

8 Caplets



Daytime Relief

Vicks DayQuil* Severe

davtime Severe cold & flu

Acetaminophen, Phenylephrine HCI, Dextromethorphan HBr, Gualfenesin

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

Alcohol Free/

Max Strength



16 Caplets

Nighttime Relief

Compare to Vicks*NyQuil* Severe

nighttime Severe cold & flu

Acetaminophen, Phenylephrine HCl, Doxylamine Succinate, Dextromethorphan HBr

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

Alcohol Free

Max Strength



8 Caplets

N ig httime Severe Cold & Flu Drug Facts Active ingredients (in each caplet) Rain e lëvedever reducer......Cough suppres sant.......Anthistamine Ac etaminophen 325 mg...... Dectrone thorphan I-Br 10 mg Doxylamines is cinale 6.25 mg. Phenyleighrine HC 15 mg.......... Uses Interported y a lieves common cold füll symptoms: In madicing a tibin Interported y in Interported y in

■ Lunny rose and smeeting ■ reduces swelling of næstpassages ■ temporative restores free ritreathing through the nose ■ promotes rasal and/or sinus diahage warrunge Liver warrung: This products ontains acetsminophen. Severellier damage may occur if yout ake more than 4,000 mgo facetsminophen in 24 hours mowth other drugs

Da ytime Sever e Co ld & Flu Drug Facts

Qualienesin 200 mg...... Phenylephrine HCl 5mg..

Uses Intemporarily relieves common coloff in symptoms Inferior Uses memor any sterior common court is symptoms. In the or in color that and brought in the store of personal pressure. It must be common that and brought in that in the headach is so the head breaking through the color in minor ache and print. It has been been been supplied in the use of the color that the supplied in the color that the supplied in the color that the color that

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DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN
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Nyaliriô Savere.
Distributed by: Perrigo
Allegan, MI 49010
GLUTEN FREE



Drug Facts (continued)

containing as stamhoghen 🔳 3 or more at cholochrinks every day whiteusing this product Allergy alert: Acetamhoghen may cause savore skin reactions. Symptoms may indude :

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Donotuse with any other diagonatains, a stammorphini prescription or norphis scription of norphis scription. If you are not use whether a drug contains as deminother, as kind of the pharmacts. If you are now taking a prescription monomine outdoes inhibitor (MAO) pharmacts. If you are now taking a prescription monomine outdoes inhibitor (MAO) for a demand a finite or a definition of a disease), or for 2 weeks a their stopping the MPO drug, thy outdonother or if your person in drug contains an MAO, as kado to or pharmacts to be a taking his product. If you there ever had an aller gice as tion to this productor any of its irgressions.

Ask adoctor before use if you have ■ Iverdisease ■ heart disease ■ middets high blood possure = throid disease = glanome = cough that occurs with too much thigm through = abeating problems. chasem by sens or chronic tracifits = per sistent or thonic cough such accurs with smoking, ashma, or emply sens a butter of the cough such accurs with smoking, ashma, or emply sens a butter of the cough such accurs with smoking, ashma, or emply sens a butter of the cough such accurs with smoking, ashma, or emply sens a butter of the cough such accurs with smoking, ashma, or emply sens a butter of the cough such accurs with smoking ashma, or emply sens a butter of the cough such accurs with smoking ashma, or emply sens a butter of the cough such accurs with smoking ashma and accurs with smoking as the cough sense of the cough such accurate the cough sense of the cough sens

Ask ad octor or pharm acist before use if you are ■ taking sedutives or tranquilizers ■ taking the blood thinning of up warfarin

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Stopus eand ask a doctor if mayouget nevous, dizzyorsleep bas mapain, nas di congasting or coughing as worse or lasts more than 7 days malever pets worse or lasts more than 3 days maderas or seeling soverant man new symptoms cour macough comes backoroccus within as hor he ada dhe frattasts. These could be signs of a serious condition

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Drug Facts (continue d)

Marnings
Liver warning: This products orbits a cots miniphen. See as liver damage may occur if youtable is more than 4,000 mg of a cetaminophen in 24 hours is withouther daugs containing acetaminophen is 3 or more abdrided orbits every day white using the product. Allergrapher: Acetaminophen may cause see either actions. Symptoms may hoube it is shinded ning is this as is as abilits skinn action occurs, stopus and seek medical halp rights way. Soreth mat warning: I soe it host is weep, per sists for more than 2 days, a baccompanied or blowwoodly lace, he adoch, rath, rate acrowing, consults a door promptly.

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Ask adoctorb efore use fyou have ■ thyroid disease ■ diabeles ■ I ver desase ■ heat disease ■ light bod pressuse ■ trouble urinsting due to ar eilar gelposate bejland ■ cough fratoccurs with bomne hightig microuse ■ pase tear for the ric cough suchas occurs with smoking, a sthma, choric bronchilis, or emphysiona Ask adoctoror pharmacist before use if you are taking the blood thinning drug warfarin

When using this product do not us e moret handirected

Stop useandaska doctorif wyou opinerwous dizzy orsleoples main nasaloong stion, or oughgets wo seor lasts more than 7 days were gets worse or lasts more than 5 days we neches or swalling is pearly were symptoms cour we ough cent shock or occurs with a shorthead acte that lasts. The second besigns of a serious condition we

Directions In take only as die ded-see over dose warring

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adults & children 12 yrs & over | 2 capte is with water every 4 hrs children 4 to under 12 yrs askadocto

Other information ustore at 20-29 C 68-77 °F)

Inactive ingredients or povidoną D&Cydbw no 10 aluminum laie, D&C blue no.1 aluminum laie, FD&C blue no.2 aluminum laie, D&C ydbw no 6 aluminum laie, magresium se ar ale, microcys tall necalblose, pole thylanegly col polyviny labchd, povidore, pa gdatnizad stardn, sib on doxide, sekario scib, tab, litanium doxide

Questions or comments? 1-800-719-9260

Drug Facts (continued)

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Directions ■ take only as directed - see one ndo sew ■ do not exceed 4dos as per 24 has

adults &children 12 yrs & over | 2caplets with water every 4hrs children 4 tounder 12 yrs askadodor children under4 vrs do not use

Other information ■ each caplet contains:sedium 4mg ■ store at 2025°C (68-77°F)

BASIC CARE DAYTIME NIGHTTIME SEVERE COLD AND FLU

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

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0113-7301

Packaging

l	# Item Code Package Description		Marketing Start Date	Marketing End Date
l	1 NDC:0113-7301-90	1 in 1 CARTON; Type 0: Not a Combination Product	0 1/16/20 19	

Quantity of Parts

Quan	Quantity of Farts				
Part #	Package Quantity	Total Product Quantity			
Part 1	4 BLISTER PACK	8			
Part 2	8 BLISTER PACK	16			

Part 1 of 2

NIGHTTIME SEVERE COLD AND FLU

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

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D) **ACETAMINOPHEN** 325 mg **DEXTRO METHO RPHAN HYDRO BRO MIDE** (UNII: 9 D2RTI9 KYH) **DEXTROMETHORPHAN** 10 mg (DEXTROMETHORPHAN - UNII:7355X3ROTS) **HYDROBROMIDE** DO XYLAMINE SUCCINATE (UNII: V9 B19 B5Y12) (DO XYLAMINE - UNII: 95Q B77JKPL) DO XYLAMINE SUCCINATE 6.25 mg PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -PHENYLEPHRINE 5 mg UNII:1WS297W6MV) HYDROCHLORIDE

Inactive Ingredients			
Ingredient Name	Strength		
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960 MK)			
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)	
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
PO VIDO NE (UNII: FZ989 GH94E)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics			
Color	GREEN	Score	no score
Shape	OVAL	Size	19 mm
Flavor		Imprint Code	L5Y5
Contains			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	4 in 1 CARTON			
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

DAYTIME SEVERE COLD AND FLU

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
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: 6840 1960 MK)			
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
MALTO DEXTRIN (UNII: 7CVR7L4A2D)			
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)			
POLYVINYL ALCOHOL (UNII: 532B59J990)			
PO VIDO NE (UNII: FZ989 GH94E)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			

Product Characteristics			
Color	RED	Score	no score
Shape	OVAL	Size	19 mm
Flavor		Imprint Code	L922
Contains			

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	8 in 1 CARTON				
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	0 1/16/20 19				

Labeler - L. Perrigo Company (006013346)

Revised: 3/2019 L. Perrigo Company