

**DAYTIME COLD AND FLU SEVERE AND NIGHTTIME COLD AND FLU SEVERE-
acetaminophen, dextromethorphan hydrobromide, guaifenesin, doxylamine succinate,
phenylephrine hydrochloride
Topco Associates LLC**

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.

DayTime Cold & Flu Severe and NightTime Cold & Flu Severe

Active ingredients (in each softgel)

Active ingredients for DayTime

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Active ingredients for Nighttime

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

Purposes

DayTime

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Nighttime

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

- temporarily relieves common cold/flu symptoms:
- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- cough to help you sleep (**Nighttime only**)

- minor aches & pains
 - headache
 - fever
 - sore throat
 - runny nose & sneezing (**Nighttime only**)
-
- 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. (**Daytime only**)

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4 doses in 24 hrs, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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.

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.

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.
- to make a child sleep (**Nighttime only**)

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma (**Nighttime only**)
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers (**Nighttime only**)
- taking the blood thinning drug warfarin.

When using this product

- **do not use more than directed**

Nighttime only:

- 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:

Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. 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 hrs

Dosing for Daytime

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

Dosing for Nighttime

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

- **when using other Nighttime or Daytime products, carefully read each label to ensure correct dosing**

Other information

- store at room temperature and avoid excessive heat

Inactive ingredients

Daytime: FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special, and white edible ink

Nighttime: D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special, and white edible ink

Questions or comments?

Call toll free: **1-888-423-0139**

Principal Display Panel - Carton Label

TopCare DayTime Cold & Flu and NightTime Cold & Flu

NDC 36800-412-04

*Compare to the active ingredients in Vicks[®] DayQuil[®] Severe and NyQuil[®] Severe Cold and Flu

Drug Facts (continued)

Active Ingredients for Daytime
 (in each softgel)
 Hydroxyzine HCl 5 mg
 Dextromethorphan HBr 10 mg
 Doxylamine Succinate 2.5 mg
 Phenylephrine HCl 5 mg
 Head decongestant

Active Ingredients for Nighttime
 (in each softgel)
 Hydroxyzine HCl 5 mg
 Dextromethorphan HBr 10 mg
 Doxylamine Succinate 2.5 mg
 Phenylephrine HCl 5 mg
 Head decongestant

DO NOT TAKE THESE PRODUCTS AT THE SAME TIME

Other Information
 ■ Look at other ingredients (15-09-85) and avoid certain foods.
 ■ When using other daytime or nighttime products, carefully read each label for the active ingredient.
 ■ Do not use if you are taking other daytime or nighttime products.
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Drug Facts (continued)

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 (in each softgel)
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Active Ingredients for Nighttime
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 Doxylamine Succinate 2.5 mg
 Phenylephrine HCl 5 mg
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SPECIAL VALUE! COMBINATION PACK

TopCare. health.

Alcohol Free
 Acetaminophen Free
 Non-Drowsy

COMPARE TO VICKS® DAYGEL® SEVERE ACTIVE INGREDIENTS*

MAXIMUM STRENGTH RELIEF

Day Time Cold & Flu SEVERE

PAIN RELIEVER- FEVER REDUCER
ACETAMINOPHEN
 COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr
 EXPECTORANT - GUAIFENESIN
 NASAL DECONGESTANT - PHENYLEPHRINE HCl

12 SOFTGELS**
 Liquid Filled Capsules

TopCare. health.

Alcohol Free
 Acetaminophen Free
 Non-Drowsy

COMPARE TO VICKS® NYGEL® SEVERE ACTIVE INGREDIENTS*

MAXIMUM STRENGTH RELIEF

Nite Time Cold & Flu SEVERE

PAIN RELIEVER- FEVER REDUCER
ACETAMINOPHEN
 COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr
 ANTIHISTAMINE - DOXYLAMINE SUCCINATE
 NASAL DECONGESTANT - PHENYLEPHRINE HCl

12 SOFTGELS**
 Liquid Filled Capsules

*The products not manufactured or distributed by Procter & Gamble and listed "Vicks" items sold at Rite Aid.

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Other Information
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Drug Facts (continued)

Other Information
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DAYTIME COLD AND FLU SEVERE AND NIGHTTIME COLD AND FLU SEVERE			
acetaminophen, dextromethorphan hydrobromide, guaifenesin, doxylamine succinate, phenylephrine hydrochloride kit			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-412

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-412-04	1 in 1 CARTON; Type 0: Not a Combination Product	06/28/2016	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	12
Part 2	1 BLISTER PACK	12

Part 1 of 2**DAYTIME COLD AND FLU SEVERE**

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride capsule, liquid filled

Product Information

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
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	orange (clear)	Score	no score
Shape	capsule (oblong)	Size	26mm
Flavor		Imprint Code	PC26
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
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	06/28/2016	

Part 2 of 2

NIGHTTIME COLD AND FLU SEVERE

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled

Product Information

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
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
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	green (clear)	Score	no score
Shape	capsule (oblong)	Size	20mm
Flavor		Imprint Code	PC22
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
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	06/28/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/28/2016	

Labeler - Topco Associates LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(36800-412) , analysis(36800-412)

Revised: 11/2019

Topco Associates LLC