SEVERE COLD AND FLU DAYTIME NON DROWSY NIGHTTIME- acetaminophen, dextromethorphan hydrobromide,guaifenesin, phenylephrine hydrochloride / acetaminophen, dextromethorphan hydrobromide, 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 NON DROWSY Severe Cold & Flu NIGHTTIME Severe Cold & Flu

Daytime and Nighttime SEVERE COLD AND FLU

Drug Facts

Active ingredients (in each softgel)	**Purposes**
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 & pressure
■ cough due to minor throat & bronchial irritation
■ minor aches & 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 4 doses in 24 hours, 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

Drug Facts (continued)

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 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.

Drug Facts (continued)

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 hours

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

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

Other information

■ store at room temperature

Inactive ingredients

FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

NIGHTTIME SEVERE COLD & FLU SOFTGELS

Drug Facts

Active ingredients (in each softgel) Purposes
Acetaminophen 325 mg.....Pain reliever/fever reducer
Dextromethorphan HBr 10 mg.....Cough suppressant
Doxylamine succinate 6.25 mg.....Antihistamine
Phenylephrine HCl 5 mg.....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 ■ minor aches & pains ■ headache
■ fever ■ sore throat ■ runny nose & 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 doses in 24 hours, 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

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.

NIGHTTIME SEVERE COLD & FLU SOFTGELS

Drug Facts (continued)

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

Ask a doctor before use if you have

■ liver disease ■ heart disease ■ high blood pressure
■ thyroid disease ■ diabetes ■ glaucoma
■ cough that occurs with too much phlegm (mucus)
■ a breathing problem or chronic cough that lasts or 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
■ 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

NIGHTTIME SEVERE COLD & FLU SOFTGELS

Drug Facts (continued)

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 hours

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

Other information

store at room temperature

Inactive ingredients

D&C Yellow #10, FD&C Blue #1, gelatin, glycerin, polyethylene glycol 400, povidone K30, propylene glycol, purified water, shellac, sorbitol sorbitan, sodium hydroxide, titanium dioxide

Questions or comments?

Call toll free: 1-888-333-9792

PRINCIPAL DISPLAY PANEL

DAY & NIGHT PACK

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

DAYTIME • NON-DROWSY

Severe
Cold & Flu
ACETAMINOPHEN /
PAIN RELIEVER / FEVER REDUCER
DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT
GUAIFENESIN / EXPECTORANT
PHENYLEPHRINE HCl / NASAL DECONGESTANT

MAXIMUM STRENGTH

ACTUAL SIZE

16SOFTGELS

NIGHTTIME

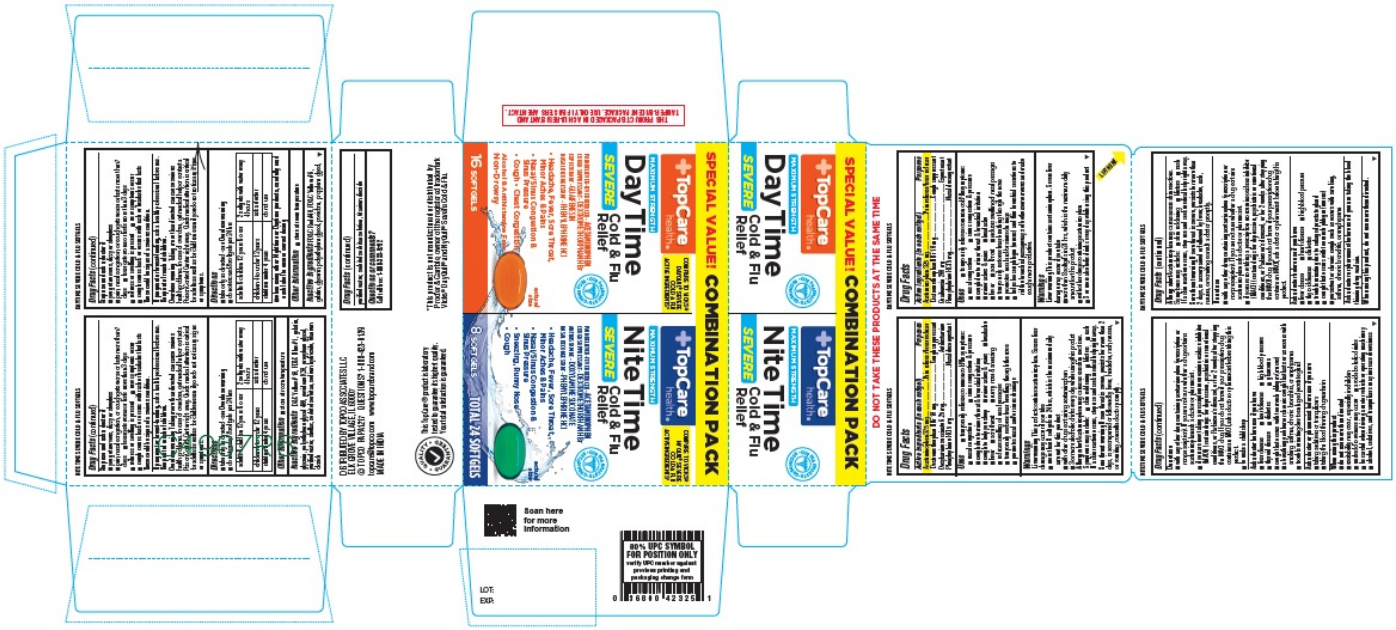
Severe
Cold & Flu
ACETAMINOPHEN /
PAIN RELIEVER / FEVER REDUCER
DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT
DOXYLAMINE SUCCINATE / ANTIHISTAMINE
PHENYLEPHRINE HCl / NASAL DECONGESTANT

MAXIMUM STRENGTH

ACTUAL SIZE

8SOFTGELS

24 SOFTGELS



SEVERE COLD AND FLU DAYTIME NON DROWSY NIGHTTIME

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

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-667

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-667-24	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	10/31/2019	

Quantity of Parts

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

Part 1 of 2

SEVERE COLD AND FLU DAYTIME NON-DROWSY

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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	**Score**	no score
Shape	OVAL (OBLONG)	**Size**	20mm
Flavor		**Imprint Code**	341
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 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	10/31/2019	

Part 2 of 2

SEVERE COLD AND FLU NIGHTTIME

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: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	**Score**	no score
Shape	OVAL (OBLONG)	**Size**	20mm
Flavor		**Imprint Code**	116
Contains			

Packaging

	Item		Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 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	10/31/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/31/2019	

Labeler - TopCo Associates LLC (006935977)

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