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

TopCare® health Day Time and Nite Time SEVERE Cold & Flu Relief COMBINATION PACK

DAY TIME SEVERE COLD AND FLU RELIEF

Drug Facts

Active ingredients (in each softgel)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Purposes

Pain reliever/fever reducer Cough suppressant Expectorant 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 8 softgels 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

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 • glaucoma • 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; taking sedatives of tranquilizers.

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.

Directions

- take only as directed
- do not exceed 8 softgels per 24 hrs

adults & children 12	2 softgels
yrs & over	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)
- protect from light, heat and moisture

Inactive ingredients

edible printing ink, FD&C blue no.1, FD&C red no.40, gelatin, glycerin, polyethylene glycol 400, povidone K30, propylene glycol, purified water, sorbitol sorbitan solution

Questions or Comments?

Call **1-888-423-0139**

NITE TIME SEVERE COLD AND FLU RELIEF

Drug Facts

Active ingredients (in each softgel)

Acetaminophen 325 mg Dextromethorphan HBr 10 mg Doxylamine succinate 6.25 mg Phenylephrine HCl 5 mg

Purposes

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 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 8 softgels 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.

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 • glaucoma • trouble urinating due to enlarged prostate gland • 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

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.

Directions

- take only as directed
- do not exceed 8 softgels per 24 hrs

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

Other information

- store at 20-25°C (68-77°F)
- protect from light, heat and moisture

Inactive ingredients

edible printing ink, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol 400, povidone K30, propylene glycol, purified water, sorbitol sorbitan solution

Questions or comments?

Call **1-888-423-0139**

COMBINATION PACK

COMPARE TO VICKS[®] DAYQUIL ™ SEVERE COLD & FLU ACTIVE INGREDIENTS*

COMPARE TO VICKS[®] NYQUIL ™ SEVERE COLD & FLU ACTIVE INGREDIENTS*

MULTI-SYMPTOM RELIEF

Antihistamine Free

DO NOT TAKE THESE PRODUCTS AT THE SAME TIME

TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

*These products are not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® DayQuil® & NyQuil® Severe

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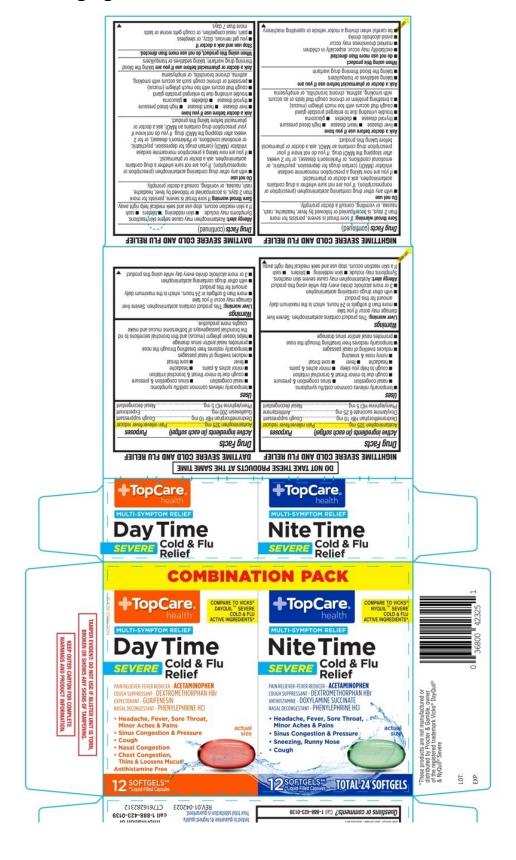
PRODUCT OF UNITED ARAB EMIRATES

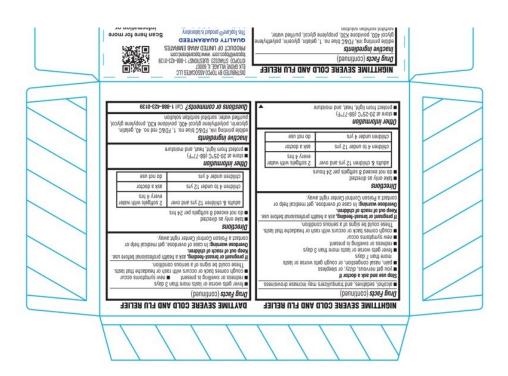
QUALITY GUARANTEED

This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

REV.01-042023

Packaging





DRUG FACTS LABEL

NIGHTTIME SEVERE COLD AND FLU RELIEF

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 HCI 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 8 softgels 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.

DAYTIME SEVERE COLD AND FLU RELIEF

Drug Facts

Active ingredients (in each softgel)	Purposes
Acetaminophen 325 mg	.Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	
Guaifenesin 200 mg	
Phenylephrine HCI 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 8 softgels 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

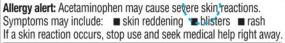
Drug Facts (continued)

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

Drug Facts (continued)



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.

with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

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
 glaucoma
- trouble urinating due to enlarged prostate gland
- 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

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

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
 glaucoma
- 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; taking sedatives or tranquilizers

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

Drug Facts (continued)

■ 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.

Directions

- take only as directed
- do not exceed 8 softgels per 24 hours

adults & children 12 yrs and over	2 softgels 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)
- protect from light, heat, and moisture

Drug Facts (continued)

- 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.

Directions

- take only as directed
- do not exceed 8 softgels per 24 hrs

adults & children 12 yrs and over	2 softgels 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)
- protect from light, heat, and moisture

Inactive ingredients

edible printing ink, FD&C blue no. 1, FD&C red no. 40, gelatin, glycerin, polyethylene glycol 400, povidone K30, propylene glycol, purified water, sorbitol sorbitan solution

Questions or comments? Call 1-888-423-0139

Drug Facts (continued)

Inactive ingredients

edible printing ink, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol 400, povidone K30, propylene glycol, purified water, sorbitol sorbitan solution

Questions or comments? Call 1-888-423-0139

COLD AND FLU SEVERE DAYTIME/NIGHTTIME

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-823
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Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:76162-823- 12	1 in 1 CARTON; Type 0: Not a Combination Product	11/03/2023	

Quant	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

TOPCARE DAY TIME SEVERE COLD AND FLU

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

Product Information		
Item Code (Source)	NDC:76162-811	
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 Ingredients			
Ingredient Name	Strength		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GELATIN, UNSPECIFIED (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: 6092ICV9RU)	

Product Characteristics				
Color orange Score no score				
Shape	OVAL	Size	21mm	
Flavor		Imprint Code	811	
Contains				

P	Packaging					
#	# Item Package Description		Marketing Start Date	Marketing End Date		
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product				

Marketing Information					
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date					
OTC Monograph Drug	M012	11/03/2023			

Part 2 of 2

TOPCARE NITE TIME SEVERE COLD AND FLU

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

Product Information Item Code (Source) NDC:76162-812 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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN, UNSPECIFIED (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: 6092ICV9RU)	

Product Characteristics				
Color green Score no score				
Shape	OVAL	Size	20mm	
Flavor		Imprint Code	812	
Contains				

l	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
OTC Monograph Drug	M012	11/03/2023		

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
OTC Monograph Drug	M012	11/03/2023		

Labeler - Topco Associates LLC (006935977)

Revised: 11/2023 Topco Associates LLC