

TOPCARE HEALTH NON DROWSY DAYTIME COLD AND FLU RELIEF AND NIGHTTIME COLD AND FLU RELIEF DAY AND NIGHT COMBO PACK- acetaminophen ,dextromethorphan hydrobromide and phenylephrine hcl ,acetaminophen,dextromethorphan hbr,doxylamine succinate TopCare Health

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.

TopCare health™ Day and Night Combination Pack Non-Drowsy Daytime Cold and Flu Relief Single Serve Cups Nighttime Cold and Flu Relief Single Serve Cups

Drug Facts Daytime Cold & Flu Relief

Active ingredients (in each single serve cup)	Purposes
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 20 mg	Cough suppressant
Phenylephrine HCl 10 mg	Nasal decongestant

Drug Facts Nighttime Cold & Flu Relief

Active ingredients (in each single serve cup)	Purposes
Acetaminophen 650 mg	Pain reliever/Fever reducer
Dextromethorphan HBr 30 mg	Cough suppressant
Doxylamine succinate 12.5 mg	Antihistamine

Uses

Daytime

temporarily relieves common cold/flu symptoms:

- nasal congestion
- cough due to minor throat & bronchial irritation
- sore throat
- headache
- minor aches & pains
- fever

Nighttime

temporarily relieves common cold/flu symptoms:

- cough due to minor throat & bronchial irritation
- sore throat
- headache
- minor aches & pains
- fever
- runny nose & sneezing

Warnings

Liver warning:

Daytime

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 daily while using this product

Allergy Alert: Acetaminophen may cause severe skin reaction. Symptom may include:

- **Skin reddening**
- **Blisters**
- **Rash**

If a skin reaction occurs, stop use and seek medical help right away.

Nighttime

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 reaction. Symptom may include:

- **Skin reddening**
- **Blisters**
- **Rash**

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning:

Daytime

If sore throat is severe, lasts for more than 2 days, is accompanied with or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Nighttime

If sore throat is severe, lasts for more than 2 days, is accompanied with or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

Daytime

Nighttime

- with any other products 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 drugs. If you do not know if your

prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Nighttime

Ask a doctor before use if you have

Daytime

- liver disease
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- 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, or emphysema

Nighttime

Ask a doctor or pharmacist before use if you are

Daytime

taking the blood thinning drug warfarin.

Nighttime

taking sedatives or tranquilizers
taking the blood thinning drug warfarin

Daytime: When using this product, do not use more than directed.

Nighttime

- 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, & tranquilizers may increase drowsiness

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 5 days(children) or 7 days(adults)
- 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.

Nighttime

- pain 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 care professional before use.

Keep out of reach of children.

Daytime

In case of overdose, get medical help or contact a Poison Control Center right away at 1-800-222-1222. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Nighttime

In case of overdose, get medical help or contact a Poison Control Center right away at 1-800-222-1222. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

Daytime

- take only as directed - see Overdose warning
- do not exceed 4 doses per 24 hours

adults & children 12yrs & over	one cup every 4 hrs
children under 12yrs	do not use

- place single-serve cup in compatible brewer
- use a minimum of 8 oz of water
- when finished, the single serve cups are hot and may drip. Tilt the cup during removal to avoid dripping.
- DO NOT REMOVE THE FOIL SEAL as the cup will not work properly in any single serve compatible brewer and could result in hot water burns.
- Flush brewer after use

Nighttime

adults & children 12yrs & over	one cup every 6 hrs
children under 12yrs	do not use

- place single-serve cup in any compatible brewer
- use a minimum of 8 oz of water
- when finished, the single serve cups are hot and may drip. Tilt the cup during removal to avoid dripping.

Other information

Daytime

- store at room temperature

Nighttime

Inactive ingredients

Daytime

citric acid, FD&C Red No. 40, flavors, isomalt, silica, sucralose

Nighttime

citric acid, FD&C Yellow No.6, flavors, isomalt, silica, sucralose

Questions or comments?

Daytime

1-866-467-2748

Nighttime

1-866-467-2748

PRINCIPAL DISPLAY PANEL

DAY & NIGHT COMBINATION PACK

TopCare Health™

NDC 36800-562-08

COMPARE TO THE ACTIVE INGREDIENTS IN VICKS® DAYQUIL® COLD & FLU*

Non-Drowsy

Daytime

Cold & Flu Relief

Single serve

Cups

COMPATIBLE WITH KEURIG® K- CUP Brewers & Keurig 2.0 Brewing System, Realcup® Brewers, Remington Icoffe® Express™ Brewers and other single-serve pod machine and personal cup brewers,

Day Time Cold & Flu

Pain reliever/Fever reducer, ACETAMINOPHEN

Cough suppressant

DEXTROMETHORPHAN Habra

Nasal decongestant

PHENYLEPHRINE HCl

Relieves:

- Headache, fever, sore throat
- Minor aches & pains
- Nasal congestion
- Cough

Berry Flavor infused with Menthol & Green Tea Flavors

Naturally and Artificially Flavored

Alcohol free

4 DAYTIME CUPS

Compare to the active ingredients in Vicks® NyQuil® Cold & Flu*

Nighttime

Cold & Flu Relief

Single Serve Cups

K-CUP®/REAL CUP® POD COMPATIBLE

ACETAMINOPHEN

Pain reliever/Fever reducer

DEXTROMETHORPHAN HBr

Cough suppressant

DOXYLAMINE SUCCINATE

Antihistamine

Relieves:

- **Headache, fever, sore throat**
 - **Minor aches and pains**
 - **Sneezing, runny Nose**
 - **Cough**
- Honey Lemon Flavor Infused Chamomile & White Tea Flavors**

4 NIGHTTIME CUPS

8 TOTAL SINGLE SERVE CUPS

Our single serve cold and flu relief cups are a warm and easy way to feel better fast. Just use our cups as you would any other single serve cup in your single serve machine for a great-tasting, flu-relieving drink anytime. Whether you need a non-drowsy way to get through a long day ahead, or you are finally tucking yourself into bed at night, take a moment and toast to relief.

***This product is not manufactured or distributed by Procter and Gamble Company, owner of the registered trademark Vicks® DayQuil® Cold & Flu and Vicks® NyQuil® Cold & Flu.**

†COMPATIBLE WITH KEURIG® K-CUP® BREWERS & Keurig 2.0 BREWING SYSTEMS.

THIS PRODUCT IS NOT AFFILIATED WITH KEURIG, INC.

Distributed by: TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

©TOPCO RARA0219

QUESTIONS? 1-888-423-0139

topcare@topco.com

www.topcarebrand.com

Quality Guarantee

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

PATENT PENDING

TAMPER EVIDENT POUCH: THIS PACKAGE IS SAFETY SEALED & CHILD RESISTANT. PRODUCT IS PACKAGED IN INDIVIDUAL SEALED POUCHES. DO NOT USE IF SEALED CUP IS TORN AND BROKEN.

READ ALL WARNINGS AND DIRECTIONS ON CARTON BEFORE USE .KEEP CARTON FOR REFERENCE, DO NOT DISCARD.

DO NOT TAKE BOTH PRODUCTS AT THE SAME TIME OR TAKE MORE THAN 4 DOSES IN ANY 24 -HOUR PERIOD.

DO NOT TAKE A DOSE OF THE NIGHTTIME PRODUCT SOONER THAN 4 HOURS AFTER THE LAST DOSE OF DAYTIME PRODUCT UNLESS DIRECTED BY DOCTOR.



TOPCARE HEALTH NON DROWSY DAYTIME COLD AND FLU RELIEF AND NIGHTTIME COLD AND FLU RELIEF DAY AND NIGHT COMBO PACK

acetaminophen ,dextromethorphan hydrobromide and phenylephrine hcl ,acetaminophen,dextromethorphan hbr,doxylamine succinate kit

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-562	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-562-08	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	03/06/2019	
Quantity of Parts				
Part #	Package Quantity	Total Product Quantity		
Part 1	4 CUP	4		
Part 2	4 CUP	4		
Part 1 of 2				
TOPCARE HEALTH DAYTIME COLD AND FLU RELIEF DAYTIME				
acetaminophen ,dextromethorphan hydrobromide and phenylephrine hcl powder, for solution				

Product Information**Route of Administration** ORAL**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ISOMALT (UNII: S870P55O2W)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	PINK	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 in 1 KIT		
1		1 in 1 CUP; 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	03/06/2019	

Part 2 of 2**TOPCARE HEALTH NIGHTTIME COLD AND FLU RELIEF NIGHTTIME**

acetaminophen,dextromethorphan hbr,doxylamine succinate powder, for solution

Product Information**Route of Administration** ORAL**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg
DOXYLAMINE SUCCINATE (UNII: V9B19B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ISOMALT (UNII: S870P55O2W)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	ORANGE	Score	
Shape		Size	
Flavor	HONEY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 in 1 KIT		
1		1 in 1 CUP; 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	03/06/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/06/2019	

Labeler - TopCare Health (006935977)