

**NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled
Strive Pharmaceuticals Inc.**

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.

RIGHT REMEDIES NightTime Cold & Flu

Drug Facts

Active ingredients (in each softgel)

Acetaminophen 325 mg
Dextromethorphan HBr 15 mg
Doxylamine succinate 6.25 mg

Purpose

Pain reliever/Fever reducer
Cough suppressant
Antihistamine

Uses

temporarily relieves common cold/flu symptoms: • cough due to minor throat & bronchial irritation • sore throat • headache • minor aches & pains • fever • runny nose and sneezing

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 daily 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
- 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, & tranquilizers may increase drowsiness

Stop use and ask a doctor if

- 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 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.

Prompt medical attention is critical for adults as well as 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

adults and children 12 yrs & over	2 softgels with water every 6 hrs
children 4 to under 12	ask a doctor
children under 4 yrs	do not use

Other information

- store at room temperature between 20-25°C (68-77°F)

Inactive ingredients

D&C yellow #10, edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, purified water, sorbitol sorbitan solution

Questions or comments

1-888-577-8033 Monday - Friday 8am - 4pm EST

Compare to the active ingredients of **Vicks® NyQuil™** Cold & Flu Relief LiquiCaps™*

RIGHT REMEDIES

READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

*This product is not manufactured or distributed by Procter & Gamble Company, owner of the registered trademarks Vicks® and NyQuil™.

Distributed by: Strive Pharmaceuticals Inc., East Brunswick, NJ 08816

Product of UAE

Packaged and Quality Assured in the USA

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

REV.00-072022

Packaging

Compare to the active ingredients of Vicks[®] NyQuil™ Cold & Flu Relief LiquiCaps™

NDC 70692-808-48

NightTime Cold & Flu

Acetaminophen 325 mg
Pain reliever/ Fever reducer
Dextromethorphan HBr 15 mg
Cough Suppressant
Doxylamine Succinate 6.25 mg
Antihistamine

48 softgels

temporarily relieves common cold/flu symptoms: headache, fever, sore throat, minor aches and pains, runny nose, sneezing, and cough

RIGHT REMEDIES

NightTime Cold & Flu

Acetaminophen 325 mg
Pain reliever/ Fever reducer
Dextromethorphan HBr 15 mg
Cough Suppressant
Doxylamine Succinate 6.25 mg
Antihistamine

temporarily relieves common cold/flu symptoms: headache, fever, sore throat, minor aches and pains, runny nose, sneezing, and cough

READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Drug Facts	Purpose
Active ingredients (in each softgel)	
Acetaminophen 325 mg.....	Pain reliever/Fever reducer
Dextromethorphan HBr 15 mg.....	Cough suppressant
Doxylamine succinate 6.25 mg.....	Antihistamine

Uses
temporarily relieves common cold/flu symptoms: ■ cough due to minor throat & bronchial irritation ■ sore throat ■ headache ■ minor aches & pains ■ fever ■ runny nose and sneezing

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 daily 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 ■ 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, & tranquilizers may increase drowsiness

Stop use and ask a doctor if ■ 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 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. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Drug Facts (continued)

Directions
■ take only as directed - see overdose warning
■ do not exceed 4 doses per 24 hrs
adults and children 12 yrs & over 2 softgels with water every 6 hrs
children 4 to under 12 ask a doctor
children under 4 yrs do not use

Other information
■ store at room temperature between 20-25°C (68-77°F)

Inactive ingredients
D&C yellow #10, edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, purified water, sorbitol sorbitan solution

Questions or comments
1-888-577-8033 Monday - Friday 8am - 4pm EST

This product is not manufactured or distributed by Procter & Gamble Company, owner of the registered trademarks Vicks[®] and NyQuil™.

Distributed by: Strive Pharmaceuticals Inc., East Brunswick, NJ 08816
Product of UAE
Packaged and Quality Assured in the USA

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



3 70692 00053 5

CT7069280848
REV.00-07/2022

DRUG FACTS TABLE

Drug Facts	
Active ingredients (in each softgel)	Purpose
Acetaminophen 325 mg.....	Pain reliever/Fever reducer
Dextromethorphan HBr 15 mg.....	Cough suppressant
Doxylamine succinate 6.25 mg.....	Antihistamine
Uses temporarily relieves common cold/flu symptoms: ■ cough due to minor throat & bronchial irritation ■ sore throat ■ headache ■ minor aches & pains ■ fever ■ runny nose and sneezing	
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 daily 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 ■ 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, & tranquilizers may increase drowsiness	
Stop use and ask a doctor if ■ 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 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. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.	

Drug Facts (continued)	
Directions ■ take only as directed - see overdose warning ■ do not exceed 4 doses per 24 hrs adults and children 12 yrs & over 2 softgels with water every 6 hrs children 4 to under 12 ask a doctor children under 4 yrs do not use	
Other information ■ store at room temperature between 20-25°C (68-77°F)	
Inactive ingredients D&C yellow #10, edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, purified water, sorbitol sorbitan solution	
Questions or comments 1-888-577-8033 Monday - Friday 8am - 4pm EST	

NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70692-808
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	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	808
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70692-808-48	4 in 1 CARTON	04/05/2023	
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	04/05/2023	
---------------------	---------	------------	--

Labeler - Strive Pharmaceuticals Inc. (080028013)

Revised: 5/2023

Strive Pharmaceuticals Inc.