DAYTIME AND NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, doxylamine succinate

Strive Pharmaceuticals Inc.

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RIGHT REMEDIES DayTime and NightTime Cold & Flu

RIGHT REMEDIES DayTime Cold & Flu

Drug Facts

# Active ingredients (in each softgel)

Acetaminophen 325 mg Dextromethorphan HBr 10 mg Phenylephrine HCl 5 mg

## **Purpose**

Pain reliever/Fever reducer Cough suppressant Nasal decongestant

#### Uses

temporarily relieves common cold/flu symptoms: • nasal congestion • cough due to minor throat & bronchial irritation • sore throat • headache • minor aches & pains • fever

# 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, lasts for more than 2 days, occurs with or is 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 as occurs with smoking, asthma, 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.

**Stop use and ask a doctor if** • you get nervous, dizzy or sleepless

- pain, nasal congestion or cough get worse or last 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	2 softgels with water
yrs & over	every 4 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

edible white ink, FD&C red #40, FD&C yellow #6, 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

# 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 monamine 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 • 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

adulta and abildran 12	2 cofteels with water
adults and children 12	2 softgels with water
yrs & over	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**® **DayQuil™** Cold & Flu Relief LiquiCaps™\*

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

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

\*This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademark Vicks  $^{\textcircled{B}}$  DayQuil $^{\texttt{TM}}$ , NyQuil $^{\texttt{TM}}$  and LiquiCaps  $^{\texttt{TM}}$ .

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

REV.00-072022

## **Packaging**



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**Drug Facts** (continued)

Do not use 

with any other dung containing seetaminophen
(prescription or nonprescription), if you are not sure whether a drug
taking a prescription monoamine oxidese inhibitor (MAMO) (certian drugs
for depression, psychiatric or emotional conditions, or Parkinson's
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Warnings
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maximum daily amount for this product ■ with other drugs containing
acetaminophen ■ 3 or more alcoholic drinks daily while using this product
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fit is akin reaction occurs, store throat is severe, lasts for more than 2 days,
Sore throat wamings: if ore throat is severe, lasts for more than 2 days,
occurs with or is followed by tever, headache, rear, nauses, or vomitting,
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Uses temporarily relieves common cold√flu symptoms: ■ nasal congestion ■ cough due to minor aches & pains ■ fever sore throat & name fever minor sches & pains ■ fever mi

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Sore funcial warming: If sore funcial is severe, persists for more trans. A days,

se accompanied or followed by fever, headache, resh, neuses, or vorniting,
consult a doctor promptly.

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

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READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION



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

NDC 70692-809-74

# **DayTime**

Cold & Flu

Acetaminophen 325 mg
Pain reliever/ Fever reducer

Dextromethorphan HBr 10 mg Cough Suppressant

Phenylephrine HCL 5 mg

Nasal Decongestant

temporarily relieves common cold/flu symptoms: headache, fever, sore throat, minor aches and pains, nasal congestion, and cough



# **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





#### (Nighttime) Drug Facts (Daytime Drug Facts Active ingredients (in each softgel) Purpose Active ingredients (in each softgel) Purpose Acetaminophen 325 mg......Pain reliever/Fever reducer Dextromethorphan HBr 15 mg.....Cough suppressant 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: ■ cough *Uses* temporarily relieves common cold/flu symptoms: ■ nasal due to minor throat & bronchial irritation ■ sore throat ■ headache congestion ■ cough due to minor throat & bronchial irritation ■ sore throat ■ headache ■ minor aches & pains ■ fever ■ minor aches & pains ■ fever ■ runny nose and sneezing Warnings Warnings Liver warning: This product contains acetaminophen. Severe liver damage Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 4 doses in 24 hrs, which is the 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 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 sever skin reactions. Symptoms

action and the action of this day while using this product Allergy alert: Acetaminophen may cause sever 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.

Liver warning: Inis 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, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

# Drug Facts (continued) (Nighttime)

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) (certian drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stoping 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 ■ 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.

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)

(Daytime)

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) (certian drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stoping 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 as occurs with smoking, asthma, 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.

Stop use and ask a doctor if ■ you get nervous, dizzy or sleepless ■ pain, nasal congestion or cough get worse or last 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) **Drug Facts** (continued) (Nighttime) (Daytime **Directions** Directions ■ take only as directed - see overdose warning ■ take only as directed - see overdose warning do not exceed 4 doses per 24 hrs ■ do not exceed 4 doses per 24 hrs adults and children 12 yrs & over 2 softgels with water every 6 hrs adults and children 12 yrs & over 2 softgels with water every 4 hrs children 4 to under 12 ask a doctor children 4 to under 12 ask a doctor children under 4 yrs do not use children under 4 yrs do not use Other information Other information ■ store at room temperature between 20-25°C (68-77°F) ■ store at room temperature between 20-25°C (68-77°F) Inactive ingredients Inactive ingredients edible white ink, FD&C red #40, FD&C yellow #6, gelatin, D&C yellow #10, edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, glycerin, polyethylene glycol 400, povidone, propylene glycol, purified water, sorbitol sorbitan solution purified water, sorbitol sorbitan solution Questions or comments Questions or comments 1-888-577-8033 Monday - Friday 8am - 4pm EST 1-888-577-8033 Monday - Friday 8am - 4pm EST

# **DAYTIME AND NIGHTTIME COLD AND FLU**

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, doxylamine succinate kit

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70692-809

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:70692-809- 74	1 in 1 CARTON; Type 0: Not a Combination Product	04/05/2023	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	4 BLISTER PACK	32
Part 2	4 BLISTER PACK	16

# Part 1 of 2

# **DAYTIME COLD AND FLU**

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

Product Information		
Item Code (Source)	NDC:70692-807	
Route of Administration	ORAL	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	

GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6092ICV9RU)	

Product Characteristics			
Color	red	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	807
Contains			

l	Packaging				
	#	Item Code	Package Description Marketing Sta		Marketing End Date
	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 Drug	M012	04/05/2023	

# Part 2 of 2

# **NIGHTTIME COLD AND FLU**

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Product Information	
Item Code (Source)	NDC:70692-808
Route of Administration	ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg	
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (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: FZ 989GH94E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SORBITOL (UNII: 506T60A25R)		
SORBITAN (UNII: 6092ICV9RU)		

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		4 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 Drug	M012	04/05/2023			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/05/2023	

# **Labeler -** Strive Pharmaceuticals Inc. (080028013)

Revised: 1/2024 Strive Pharmaceuticals Inc.