

DAYTIME NIGHTTIME COLD FLU RELIEF- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl
FSA Store Inc. (Caring Mills)

DRUG FACTS

Active ingredients for Daytime (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Active ingredients for Nighttime (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

Purpose for Daytime

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Purpose for Nighttime

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Uses

DAYTIME

- temporarily relieves common cold and flu symptoms
 - cough due to minor throat and bronchial irritation
 - nasal congestion
 - headache
 - minor aches and pains
 - fever
 - sore throat

NIGHTTIME

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

Warnings

DAYTIME

Liver warning: These products contain acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using these products

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

Liver warning: This product contain acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg of acetaminophen in 24 hours
- 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 following by fever, headache, rash, nausea, vomiting, consult a doctor promptly.

Do not use

DAYTIME

- 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.

NIGHTTIME

- 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

DAYTIME

- liver disease
- heart disease
- diabetes
- thyroid disease
- high blood pressure
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

NIGHTTIME

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

DAYTIME

taking the blood thinning drug warfarin

NIGHTTIME

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product,

DAYTIME

do not exceed recommended dosage.

NIGHTTIME

- **do not exceed recommended dosage**
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

DAYTIME

- nervousness, dizziness or sleeplessness occur
- pain, cough, and nasal congestion gets worse or lasts more than 7 days
- redness or swelling is present
- new symptoms occur
- fever gets worse or lasts more than 3 days
- 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 headache that lasts.

These could be a 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 the recommended dose can cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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

DAYTIME

- **do not take more than directed (see Overdose warning)**
- do not take more than 4 doses in 24 hours
- swallow whole; do not crush, chew, or dissolve
- adults and children 12 years and over; take 2 softgels with water every 4 hours.
- children under 12 years: do not use

NIGHTTIME

- **do not take more than directed (see Overdose warning)**

- do not take more than 4 doses in 24 hours
- swallow whole; do not crush, chew, or dissolve
- adults and children 12 years and over: take 2 softgels with water every 6 hours
- children under 12 years: do not use

Other information

- store between 15°-30°C (59°-86°F)
- avoid excessive heat

Inactive ingredients

DAYTIME

FD&C red #40, FD&C yellow #6, gelatin, glycerin, lecithin, light mineral oil, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, white ink

NIGHTTIME

D&C yellow #10, FD&C blue #1, gelatin, glycerin, lecithin, light mineral oil, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, white ink

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

**Compare to Vicks® Dayquil® and Nyquil® Cold & Flu LiquiCaps® active ingredients

DAYTIME

Cold & Flu Relief

Pain reliever, Fever Reducer,

Cough Suppressant, Nasal Decongestant

Acetaminophen

Dextromethorphan HBr

Phenylephrine HCl

Non-Drowsy

Alcohol-free

Antihistamine-free

Softgels*

(*Liquid-filled capsules)

NIGHTTIME

Cold & Flu Relief

Pain Reliever, Fever Reducer,
Cough Suppressant, Antihistamine

Acetaminophen

Dextromethorphan HBr
Doxylamine Succinate
Alcohol-free

When using Daytime and Nighttime product, carefully read the labeling to ensure correct dosing.

Softgels

(*Liquid-filled capsules)

†This product is not manufactured or distributed by The Procter & Gamble Company. Vicks®, DayQuil, NyQuil®, and LiquiCaps® are registered trademarks of the Procter and Gamble Company.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOW SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Manufactured for FSA Stores Inc.

601 W 26th St, 3rd Floor

STE 357

DPT#24075

New York, NY 10001

Product Label

NDC 15122-101-48



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

Daytime Cold & Flu Relief

Pain Reliever, Fever Reducer, Cough Suppressant, Nasal decongestant

Acetaminophen

Dextromethorphan HBr
Phenylephrine HCl

Non-drowsy
Alcohol-free
Antihistamine-free



Actual Size

Nighttime Cold & Flu Relief

Pain Reliever, Fever Reducer, Cough Suppressant, Antihistamine

Acetaminophen

Dextromethorphan HBr
Doxylamine succinate

Alcohol-free

When using Daytime and Nighttime products, carefully read the labeling to ensure correct dosing.



Actual Size

Daytime Cold & Flu Softgel

Drug Facts (continued)

Ask a doctor before use if you have liver disease heart disease diabetes thyroid disease high blood pressure cough that occurs with too much phlegm (mucus) trouble urinating due to an enlarged prostate gland parosmia or chronic cough such 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 exceed recommended dosage.

Stop use and ask a doctor if:

- nauseous, dizzy, or sleepiness occur
- stomach pain or heartburn occurs more than 7 days
- fever gets worse or lasts more than 3 days
- 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 the recommended dose can cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick help or contact a Poison Control Center for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not take more than 4 doses in 24 hours
- swallow whole, do not crush, chew, or dissolve
- adults and children 12 years and over: take 2 softgels with water every 4 hours
- children under 12 years: do not use

Nighttime Cold & Flu Softgel

Drug Facts (continued)

Ask a doctor before use if you have liver disease glaucoma cough that occurs with too much phlegm (mucus) breathing problem or chronic cough that lasts such as occurs with smoking, asthma, chronic bronchitis, or emphysema trouble urinating due to an enlarged prostate gland

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 exceed recommended dosage

- occasionally may occur, especially in children
- severe drowsiness may occur
- avoid alcoholic drinks
- do not drink when driving a motor vehicle or operating machinery

Stop use and ask a doctor if:

- stomach pain or heartburn occurs more than 7 days
- fever gets worse or lasts more than 3 days
- 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 the recommended dose can cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick help or contact a Poison Control Center for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not take more than 4 doses in 24 hours
- swallow whole, do not crush, chew, or dissolve
- adults and children 12 years and over: take 2 softgels with water every 6 hours
- children under 12 years: do not use

Daytime Cold & Flu Softgel

Drug Facts

Purposes

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg
Cough suppressant
Pain reliever/fever reducer
Nasal decongestant

Warnings

Liver warnings: This product contains acetaminophen. Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours with other drugs containing acetaminophen

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: skin redness, blisters, rash

Some throat warnings: 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.

Nighttime Cold & Flu Softgel

Drug Facts

Purposes

Acetaminophen 325 mg
Dextromethorphan HBr 15 mg
Doxylamine succinate 6.25 mg
Cough suppressant
Pain reliever/fever reducer
Antihistamine

Warnings

Liver warnings: This product contains acetaminophen. Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours with other drugs containing acetaminophen

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: skin redness, blisters, rash

Some throat warnings: 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.



CARING MILL Daytime Nighttime Cold and Flu Relief

DAYTIME NIGHTTIME COLD FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81522-901
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81522-901-48	1 in 1 KIT; Type 0: Not a Combination Product	01/31/2023	

Quantity of Parts

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

Part 1 of 2

NIGHT TIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information

Item Code (Source)	NDC:81522-899
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: 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 (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
MINERAL OIL (UNII: T5L8T28FGP)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	PC10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		16 in 1 CARTON		
1		1 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	01/31/2023	

Part 2 of 2

DAYTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information

Item Code (Source) NDC:81522-898

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

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, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics

Color	orange	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	PC9
Contains			

Packaging

#	Item	Package Description	Marketing Start	Marketing End
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#	Code	Package Description	Date	Date
1		32 in 1 CARTON		
1		1 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	01/31/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/31/2023	

Labeler - FSA Store Inc. (Caring Mills) (049283340)

Revised: 4/2024

FSA Store Inc. (Caring Mills)