# EQUALINE DAYTIME AND NIGHTTIME COLD AND FLU RELIEF- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl United Natural Foods, Inc. dba UNFI

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.

-----

## SuperValu Inc. Daytime & Nighttime Cold & Flu Relief Drug Facts

## Nighttime Cold & Flu Active ingredients (in each 30 mL)

Acetaminophen 650 mg
Dextromethorphan HBr 30 mg
Doxylamine succinate 12.5 mg

### **Purpose**

Pain reliever/fever reducer
Cough suppressant
Antihistamine

### Uses

temporarily relieves common cold/flu symptoms:

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

## Warnings

**Liver warning:** 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
- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

### Ask a doctor before use if you have

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

## Ask a doctor or pharmacist before use if you are

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

## When using this product

- 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

- 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 (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### **Directions**

- take only as directed see Overdose warning
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

### Other information

- each 30 mL contains: sodium 38 mg
- store at 20-25°C (68-77°F)

## **Inactive ingredients**

alcohol, anhydrous citric acid, D&C yellow no. 10, FD&C green no. 3, FD&C yellow no. 6, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium. sodium citrate

### Questions or comments?

1-855-423-2630

## Daytime Cold & Flu Active ingredients (in each 15 mL)

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 and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever

## **Warnings**

Liver warning: This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

## Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an 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 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.

## 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 (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### **Directions**

- take only as directed see Overdose warning
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 4 hrs
children 6 to under 12 yrs	15 mL every 4 hrs
children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

### Other information

- each 15 mL contains: sodium 7 mg
- store at 20-25°C (68-77°F)

### Inactive ingredients

butylated hydroxyanisole, edetate disodium, FD&C yellow no. 6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum

### Questions or comments?

1-855-423-2630

## **Principal Display Panel**

**EQUALINE**®

cold & flu combo pack

compare to Vicks® DayQuil® Cold & Flu active ingredients

**EQUALINE**®

daytime cold & flu relief

acetaminophen (pain reliever/fever reducer)

dextromethorphan HBr (cough suppressant)

phenylephrine HCI (nasal decongestant)

powerful daytime relief

multi-symptom

### relieves:

- aches, fever & sore throat
- nasal congestion
- coughs

original flavor

ALCOHOL FREE • ANTIHISTAMINE FREE

compare to Vicks® NyQuil® Cold & Flu active ingredients

**EQUALINE**®

nighttime cold & flu relief

acetaminophen (pain reliever/fever reducer)

dextromethorphan HBr (cough suppressant)

doxylamine succinate (antihistamine)

powerful nighttime relief

## relieves:

- aches & fever
- runny nose
- sneezing
- cough

original flavor

ALCOHOL 10%

12 FL OZ (355mL) + 12 FL OZ (355mL) = 24 FL OZ (1.5pt) 710mL

## EQUALINE®

# daytime & nighttime cold & flu combo pack

NDC 41163-567-02

## **EQUALINE®**

cold & flu combo pack



### powerful daytime relief

multi-symptom

### relieves:

- aches, fever & sore throat
- nasal congestion
- coughs

original flavor

ALCOHOL FREE • ANTIHISTAMINE FREE

## powerful nighttime relief

### relieves:

- aches & fever
- runny nose
- sneezing
- cough

original flavor ALCOHOL 10%

12 FL OZ (355 mL)+12 FL OZ (355 mL)=24 FL OZ (1.5 pt) 710 mL





## **EQUALINE®**

# nighttime

### acetaminophen

(pain reliever/fever reducer)
dextromethorphan HBr
(cough suppressant)
doxylamine succinate
(antihistamine)

## powerful nighttime relief

### relieves:

- aches & fever
- runny nose
- sneezing
- cough

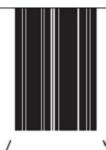


### **GLUTEN FREE**

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

\*These products are not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademarks Vicks® NyQuil® and DayQuil®. 0 41163 49177 9

56702 EL C7



### Nighttime Cold & Flu Drug Facts

Do not use

a sodium-restricted diet

When using this product

Stop use and ask a doctor If

not notice any signs or symptoms.

children 4 to under 12 yrs

■ each 30 mL contains; sodium 38 mg ■ store at 20-25°C (68-77°F)

Questions or comments? 1-855-423-2630

children under 4 yrs

Other information

Directions

Active ingredients (in each 30 mL)

Uses temporarity relieves common cold/flu symptoms:

cough due to mirror throat and bronchial irritation

sore throat headache minor aches and pains
fever runny nose and sneezing

Liver warning: This product contains acetaminophen. Severe liver damage may

Liver warming: I may product occurring the management of the court if you take

more than 4,000 mg of acetaminophen in 24 hours

with other drugs containing acetaminophen

3 or more elocholic drinks every druy while using this product
Alliergy aliert. Acetaminophen may cause severe skin reactions. Symptoms may include:

metation with readdening to blisters to rish the skin readdening to blisters to rish the skin readdening to blisters to rish skin readdening to some threat because the skin readdening to some threat because the skin readdening to read the skin readdening to read the skin readdening to read the skin readdening to readdening the skin readdening to read the skin readdening the skin readdeni

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
Parkinooris disease), or for 2 weeks after stopping the MAOI drug. If you do not
know if your prescription drug contains an MAOI, sak a doctor or pharmacist
before taking this product.

If you have ever find an allergic reaction to this product or any of its ingredients

As it a doctor or pharmacist before use if you are

taking sedatives or tranquilizers taking the blood thinning drug warfarin

If pregnant or breast-feeding, csix a health professional before use. Ke ep out of reach of children. Overdose warning: In case of overdose, get medical help or contact a Polson Control Center right twey (1-800-222-1222). Outok medical attention is critical for adults as well as for children even if you do

DIFECTIONS

make only so directed – see Overdose warming
morely use the dose cup provided
mode on the exceed 4 doses per 24 hrs
adults & children 12 yrs & over
30 mit every 6 hrs

Imactive ingredients alcohol, anhydrous citric add, D&C yellow no. 10, PD&C green no. 3, PD&C yellow no. 6, flawor, high fructose com syrup, polyethyler ghycol, propytene ghycol, purified water, saccharin socilum, socilum citrate

ask a doctor

new symptoms occur
 cough comes back or occurs with rash or headache that lasts.
 These could be signs of a serious condition.

pain or cough gets worse or lasts more than 7 days
 fever gets worse or lasts more than 3 days
 refless or swelling is present.

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

nophen 650 mg.

Dextromethorphan HBr 30 mg... Doxylamine succinate 12.5 mg.

Purpos

..Pain reliever/fever reduce .Cough suppre

Drug Facts Active ingredients (in each 15 mL) Purpose Pain relieven fever reducer Acetaminophen 325 mg...... Dextromethorphan HBr 10 mg. .Cough suppressant .Nasai decongestant

temporarity relieves common celd/flu symptoms:
nessi congestion cough due to minor throat and bronchial irritation sore throat to headache minor aches and pains fever

### Warnings

Daytime Cold & Flu

Liver warning: This product contains acetaminophen. Severe liver damage may

occur if adult takes more than 4,000 mg of scetaminophen in 24 hours in adult takes more than 5 does in 24 hours in taken with other drugs contribing acataminophen in adult has 3 or more alcoholic chinks every day white using this product. Allergy alert: Acetaminophen may cause severe exin reactions. Symptoms

Braude

sign recidening

bitsters

rash

stan recidening

bits skin reciden occurs, stop use and seek medical help right away.

Sore threat warning: if sore throat is servere, persists for more than 2 days, is
accompanied or followed by fiver; headache, rash, neuses, or vomiting, consult a

- with any other drug containing scelaminophen (prescription or nonprescription). If you are not sure whether a drug contains ac elaminophen, ask a doctor or pharmacist.
- asks doctor of premisest.

  If you are now taking a prescription monoamine oxidase inhibitor (MAOI)
  (estain drugs for depression, psychiatric, or emotional conditions, or
  Parkinsor's dasease, 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 pharmadat
  before taking this product.

  If you have ever had an allergic reaction to this product or any of its Ingredients

- Ask a doctor before use if you have

  It iver closese Internation ask Ingh blood pressure

  It tryoid closese International ask Ingh blood pressure

  It tryoid closese Ingh blood pressure

  It tryoid closese

  It tryoid clo

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 nerious, 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

cough comes back or occurs with rash or head ache 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 context a Folion Control Center right away (1-000-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

■ take only as directed — see Overdose warming ■ only use the diose cup provided ■ do not exceed 4 doses per 24 hrs adults & children 12 yrs & over 30 mL ewery 4 hrs children 6 to under 12 vrs 15 mL ewery 4 hrs children 4 to under 6 yrs children under 4 yrs

### Other information

■ each 15 mL contains: sodium 7 mg ■ store at 20-25°C (68-77°F)

Inactive ingredients butylated hydroxyanisote, edetale disodium, FD&C yellow no. 8, flavor, glycerin, merrihol, monobasic sodium phosphate, polyethyleni cytycii, propytene glycol, purified weiter, saccharin sodium, sucrose, xanthan gum

## **EQUALINE®**

## daytime cold & flu relief

### acetaminophen

(pain reliever/fever reducer) dextromethorphan HBr (cough suppressant) phenylephrine HCI (nasal decongestant)

## powertul daytime relief

## multi-symptom relieves:

- aches, fever & sore throat
- nasal congestion
- coughs



Distributed by UNFI Providence, RI 02908 USA



100% Quality Like it or let us make it right.

That's our quality promise.

855-423-2630





## **EQUALINE DAYTIME AND NIGHTTIME COLD AND FLU RELIEF**

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41163-567

Pa	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:41163-567- 02	1 in 1 CARTON; Type 0: Not a Combination Product	08/14/2012	

Quant	ity of Parts	
Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	355 mL
Part 2	1 BOTTLE	355 mL

### Part 1 of 2

## **EQUALINE NIGHTTIME COLD AND FLU RELIEF**

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

### **Product Information**

 Item Code (Source)
 NDC:41163-335

 Route of Administration
 ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 30 mL	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL	
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL	

Inactive Ingredients	
Ingredient Name	Strength

ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	

Product Characteristics			
Color	GREEN (clear, bright green)	Score	
Shape		Size	
Flavor	FRUIT (anise / cooling menthol aroma)	Imprint Code	
Contains			

l	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:41163-335- 40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing In	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341			

## Part 2 of 2

## **EQUALINE DAYTIME COLD AND FLU RELIEF**

acetaminophen, dextromethorphan hbr, phenylephrine hcl solution

<b>Product Information</b>	
Item Code (Source)	NDC:41163-656
Route of Administration	ORAL

Active Ingredient/Active Moiety			
	Ingredient Name	<b>Basis of Strength</b>	Strength
	ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg in 15 mL

<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

Inactive Ingredients	
Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	

Product Characteristics			
Color	ORANGE (clear)	Score	
Shape		Size	
Flavor	MENTHOL (with fruit)	Imprint Code	
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:41163-656- 40	355 mL in 1 BOTTLE; 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		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/14/2012	

## Labeler - United Natural Foods, Inc. dba UNFI (943556183)

Revised: 6/2023 United Natural Foods, Inc. dba UNFI