

**SINUS CONGESTION AND PAIN DAYTIME- acetaminophen and phenylephrine
hcl tablet, film coated
United Natural Foods, Inc. dba UNFI**

Equaline 44-466C

Active ingredients (in each caplet)

Acetaminophen 325 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Nasal decongestant

Uses

- temporarily relieves these symptoms associated with hay fever or other respiratory allergies, and the common cold:
 - minor aches and pains
 - headache
 - nasal congestion
 - sinus congestion and pressure
- helps decongest sinus openings and passages
- promotes sinus drainage
- helps clear nasal passages
- temporarily reduces fever

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:

- blisters
- rash
- skin reddening

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

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
- difficulty in urination due to enlargement of the prostate gland
- heart disease
- diabetes
- thyroid disease
- high blood pressure

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

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

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.

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

Directions

- **do not take more than directed**
- adults and children 12 years and over
 - take 2 caplets every 4 hours
 - swallow whole - do not crush, chew, or dissolve
 - do not take more than 10 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

1-855-423-2630

Principal Display Panel

NDC 41163-664-08

EQUALINE®

**compare to
Tylenol®
SINUS + HEADACHE**
active ingredients*

**daytime sinus
congestion & pain
acetaminophen**
(pain reliever/fever reducer)
phenylephrine HCl
(nasal decongestant)

non-drowsy

relieves:

- *sinus headache & pressure*
- *nasal congestion*

PSEUDOEPHEDRINE FREE

24 caplets

actual size

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS
OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR
SHOWS ANY SIGNS OF TAMPERING**

DISTRIBUTED BY UNFI

PROVIDENCE, RI 02908 USA

855-423-2630

*This product is not manufactured or distributed by
Johnson & Johnson Corporation, owner of the
registered trademark Tylenol® SINUS + HEADACHE.

50844 REV0721H46608

Drug Facts
 COMPLETE PRODUCT INFORMATION
 KEEP OUTER PACKAGE FOR
Active ingredients
 (in each caplet)
 Acetaminophen 325 mg Pain reliever/fever reducer
 Phenylephrine HCl 5 mg Nasal decongestant

Drug Facts (continued)
Uses
 temporarily relieves these symptoms associated with hay fever or other respiratory allergies, and the common cold: ■ minor aches and pains ■ headache ■ nasal congestion ■ sinus congestion and pressure

compare to
 Tylenol®
 SINUS + HEADACHE
 active ingredients*

NDC 41163-664-08

EQUALINE®

daytime sinus congestion & pain

acetaminophen
 (pain reliever/fever reducer)
 phenylephrine HCl
 (nasal decongestant)

non-drowsy

- relieves:
- sinus headache & pressure
 - nasal congestion

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actual size

24 caplets

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No print area
 Lot no. & Exp. Date

Drug Facts (continued)
Inactive ingredients
 com starch, crospovidone, D & C yellow #10 aluminum lake, FD & C blue #1 aluminum lake, FD & C red #40 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone,

Drug Facts (continued)
 silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide
Questions or comments? 1-855-423-2630

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
 ■ difficulty in urination due to enlargement of the prostate gland ■ liver disease ■ heart disease ■ diabetes

Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.
Directions
 ■ do not take more than directed ■ adults and children 12 years and over ■ take 2 caplets every 4 hours ■ swallow whole – do not crush, chew, or dissolve ■ do not take more than 10 caplets in 24 hours ■ children under 12 years: ask a doctor
Other information ■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
 ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
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100% Quality GUARANTEED
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B-0019E-466C-08SCR
 REV0721H46608

No F
 Glue

Print Area

Print
Area

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison professional before use.

If pregnant or breast-feeding, ask a health professional before use. These could be signs of a serious condition.

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

Stop use and ask a doctor if recommended dosage.

When using this product do not exceed taking the blood thinning drug warfarin.

Ask a doctor or pharmacist before use if you are ■ thyroid disease ■ high blood pressure

Drug Facts (continued)

help right away.

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

- hives ■ rash ■ skin reddening
- blisters ■ skin redness

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

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

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

Warnings

- helps decongest sinus openings and passages
- promotes sinus drainage
- helps clear nasal passages
- temporarily reduces fever

Drug Facts (continued)

No F
Glue

Equaline 44-466C

SINUS CONGESTION AND PAIN DAYTIME

acetaminophen and phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-664
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	17mm
Flavor	MENTHOL	Imprint Code	44;466
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-664-08	2 in 1 CARTON	07/26/2005	
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 Drug	M012	07/26/2005	

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

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(41163-664) , pack(41163-664)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(41163-664)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(41163-664)

Revised: 2/2024

United Natural Foods, Inc. dba UNFI