

EQUALINE CONGESTION RELIEF- ibuprofen, phenylephrine hcl tablet, film coated

United Natural Foods, Inc. dba UNFI

SuperValu Inc. Congestion Relief Drug Facts

Active ingredients (in each tablet)

Ibuprofen 200 mg (NSAID)*

Phenylephrine HCl 10 mg

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Nasal decongestant

Uses

- temporarily relieves these symptoms associated with the common cold or flu:
- headache
- fever
- sinus pressure
- nasal congestion
- minor body aches and pains
- reduces swelling of the nasal passages
- temporarily restores freer breathing through the nose

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin.

Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause

severe stomach bleeding.

The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- in children under 12 years of age because this product contains too much medication for children under this age
- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery
- 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

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, thyroid disease, diabetes, have trouble urinating due to an enlarged prostate gland, or had a stroke
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking any other product that contains phenylephrine or any other nasal decongestant
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
- chest pain
- trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling
- pain gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- nasal congestion lasts for more than 7 days
- symptoms continue or get worse
- redness or swelling is present in the painful area
- you get nervous, dizzy, or sleepless
- any new symptoms appear

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- **do not take more than directed**
- adults and children 12 years of age and over:
- take 1 tablet every 4 hours while symptoms persist.
- do not use more than 6 tablets in any 24-hour period unless directed by a doctor
- children under 12 years of age: do not use because this product contains too much medication for children under this age

Other information

- store at 20-25°C (68-77°F). Avoid excessive heat above 40°C (104°F).
- read all warnings and directions before use. Keep carton.

Inactive ingredients

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #2

aluminum lake, FD&C yellow #6 aluminum lake, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

1-855-423-2630

Principal Display Panel

EQUALINE®

compare to Advil® Sinus Congestion & Pain active ingredients

congestion relief

ibuprofen 200 mg

pain reliever/fever reducer (NSAID)

phenylephrine hydrochloride 10 mg

nasal decongestant tablets

sinus congestion & pain

Nasal Congestion

Headache

Sinus Pressure

Fever

Nasal Swelling

Body Aches

NON-DROWSY

actual size

20 coated tablets

ONE TABLET DOSE

EQUALINE®

NDC 41163-158-60

compare to Advil® Sinus Congestion & Pain active ingredients**

congestion relief

ibuprofen 200 mg
pain reliever/fever reducer (NSAID)
phenylephrine hydrochloride 10 mg
nasal decongestant tablets

sinus congestion & pain

- Nasal Congestion
- Sinus Pressure
- Nasal Swelling
- Headache
- Fever
- Body Aches

NON-DROWSY

20 coated tablets



actual size

ONE TABLET DOSE

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

*This product is not manufactured or distributed by Pfizer Inc., distributor of Advil® Sinus Congestion & Pain.

Drug Facts

Active ingredients (in each tablet)

ibuprofen 200 mg (NSAID)*	Pain reliever/fever reducer
Phenylephrine HCl 10 mg	Nasal decongestant

*nonsteroidal anti-inflammatory drug

Purposes

Drug Facts (continued)

Uses

- temporarily relieves these symptoms associated with the common cold or flu:
 - headache
 - fever
 - sinus pressure
 - nasal congestion
 - minor body aches and pains
 - reduces swelling of the nasal passages
- temporarily restores free breathing through the nose

Warnings

Along with: ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, blisters. If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause a severe stomach bleeding. The chance is higher if you: are age 60 or older

- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks everyday while using this product
- take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Don't use:

- in children under 12 years of age because this product contains too much medication for children under this age
- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery
- if you are now taking a prescription iron or the 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:

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver disease, kidney disease, asthma, thyroid

Drug Facts (continued)

disease, diabetes, have trouble urinating due to an enlarged prostate gland, or had a stroke. If you are taking a diuretic

Ask a doctor or pharmacist before use if you are:

- under a doctor's care for any serious condition
- taking any other product that contains phenylephrine or any other nasal decongestant
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

When using this product:

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if:

- you experience any of the following signs of stomach bleeding:
 - red or black stools
 - blood in vomit
 - blood in stool
 - have bloody or black stools
 - have stomach pain that does not get better
 - you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part of body
 - slurred speech
 - leg swelling
 - pain gets worse or lasts more than 7 days
 - fever gets worse or lasts more than 3 days
 - nasal congestion lasts for more than 7 days
 - symptoms continue or get worse
 - redness or swelling is present in the painful area
 - you get nervous, dizzy, or sleepy
 - any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause a problem in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- do not take more than directed
- adults and children 12 years of age and over:
 - take 1 tablet every 4 hours while symptoms persist.
 - do not use more than 6 tablets in any 24-hour period unless directed by a doctor
- children under 12 years of age: do not use because this product contains too much medication for children under this age

Other information

- store at 20°-25°C (68°-77°F). Avoid excessive heat above 40° C (104°F).
- read all warnings and directions before use. Keep carton.

Drug Facts (continued)

Inactive ingredients: acetaminophen, potassium, colbisdalston dioxide, croscarmellose sodium, FD&C blue #2 aluminum lake, FD&C yellow #6 aluminum lake, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, tartaric acid, sucrose, tlc, titanium dioxide

Contains 20 tablets per blister pack.

GLUTEN



15860 EL CZ

OPEN OTHER END

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Providence, RI 02908 USA

Like it or let us make it right.
That's our quality promise.
855-423-2630



CONVENIENT RECLOSING TAB



EQUALINE CONGESTION RELIEF

ibuprofen, phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-158
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BROWN (brownish-orange)	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	L158
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC 41163-158			

1	NDC:41163-158-46	10 in 1 CARTON	07/17/2015	10/31/2021
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41163-158-60	20 in 1 CARTON	03/08/2021	
2		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
ANDA	ANDA203200	07/17/2015	

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

Revised: 8/2023

United Natural Foods, Inc. dba UNFI