

EQUALINE DUAL ACTION PAIN RELIEVER- acetaminophen, ibuprofen tablet, film coated

United Natural Foods, Inc. dba UNFI

SuperValu Inc. Dual Action Pain Reliever Drug Facts

Active ingredients (in each caplet)

Acetaminophen 250 mg

Ibuprofen 125 mg (NSAID*)

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever

Uses

- temporarily relieves minor aches and pains due to:
- headache
- toothache
- backache
- menstrual cramps
- muscular aches
- minor pain of arthritis

Warnings

Acetaminophen liver damage warning:

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

- with other drugs containing acetaminophen
- more than 6 caplets in 24 hours, which is the maximum daily amount for this product
- 3 or more alcoholic drinks every day while using this product

Acetaminophen allergy alert: may cause severe skin reactions.

Symptoms may include:

- skin reddening
- blisters
- rash

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

NSAID 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.

NSAID 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

- 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 have ever had an allergic reaction to acetaminophen or any other pain reliever
- right before or after heart surgery

Ask a doctor before use if

- you have liver disease
- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, 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 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 10 days
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in 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). 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 8 hours while symptoms persist

Children under 12 years: ask a doctor

- do not take more than 6 caplets in 24 hours, unless directed by a doctor

Other information

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

Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone, ferric oxide yellow, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

1-855-423-2630

Package/Label Principal Display Panel

EQUALINE®

compare to Advil® Dual Action active ingredients

dual action pain reliever

acetaminophen 250 mg and ibuprofen (NSAID) 125 mg tablets

pain reliever

CONTAINS 2 MEDICINES

acetaminophen + ibuprofen

for aches & pains

36 caplets***

***capsule-shaped tablets

actual size

53J68 EL C1

0 41163 50423 3
DISTRIBUTED BY
UNFI
PROVIDENCE, RI 02908 USA
855-4-23-2630
Do not use if printed seal under cap is broken or missing.
GLUTEN FREE

Do not use with other medicines containing ACETAMINOPHEN; can cause liver damage.
READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Drug Facts
Active ingredients (in each caplet): **Purposes**
Acetaminophen 250 mg, Ibuprofen 125 mg (NSAID)¹, Pain reliever
¹nonsteroidal anti-inflammatory drug

Uses ■ temporarily relieves minor aches and pains due to: ■ headache ■ backache ■ toothache ■ backache ■ menstrual cramps ■ muscular aches ■ minor pain of arthritis

Warnings
Acetaminophen liver damage warning:
this product contains acetaminophen. Severe liver damage may occur if you take: ■ more than 6 caplets containing acetaminophen ■ more than 6 caplets in 24 hours, which is the maximum daily amount for this product. ■ 3 or more alcoholic drinks every day while using this product.

Acetaminophen allergy alert: may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash. If skin reaction occurs, stop use and seek medical help right away.
NSAID allergy alert: ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin.

Drug Facts (continued)

Symptoms may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock ■ skin reddening ■ rash ■ blisters ■ 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.

NSAID 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: ■ 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 have ever had an allergic reaction to acetaminophen or any other pain reliever ■ right before or after heart surgery

Ask a doctor before use if: ■ you have liver disease ■ stomach bleeding warning applies to you ■ you have problems or serious side effects from taking pain relievers ■ you have a history of stomach problems, such as heartburn ■ you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, 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 aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin ■ taking any other drug

Questions or comments?
1-855-423-2630
The product is not an analgesic or a blood thinner. It is not intended for use in children or for the treatment of pain in children. © 2014 Unifarm, Inc. All rights reserved.

US ONLY
Recycling symbols for Paper, Plastic, and Glass.
Recycling symbol for Recycled Paper.
Recycling symbol for Recycled Plastic.
Recycling symbol for Recycled Glass.

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

Drug Facts (continued)
Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, crospovidone, ferric oxide yellow, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearyl acid, sucrose, talc, titanium dioxide

Drug Facts (continued)

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 ■ big swelling ■ pain gets worse or lasts more than 10 days ■ redness or swelling is present in the painful area ■ any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in 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). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions
Adults and children 12 years and over: take 2 caplets every 8 hours with symptoms persist. Children under 12 years: ask a doctor. ■ do not take more than 6 caplets in 24 hours, unless directed by a doctor

compare to Advil® Dual Action active ingredients**
NDC 41163-103-68

EQUALINE®

dual action pain reliever

acetaminophen 250 mg and ibuprofen (NSAID) 125 mg tablets
pain reliever

CONTAINS 2 MEDICINES
acetaminophen + ibuprofen
for aches & pains

36 caplets*** ***capsule-shaped tablets



actual size

EQUALINE DUAL ACTION PAIN RELIEVER

acetaminophen, ibuprofen tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41163-103 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 250 mg |
| IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) | IBUPROFEN | 125 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|----------|
| Color | YELLOW | Score | no score |
| Shape | OVAL | Size | 14mm |
| Flavor | | Imprint Code | II |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:41163-103-68 | 1 in 1 CARTON | 03/21/2024 | |
| 1 | | 36 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:41163-103-89 | 1 in 1 CARTON | 03/21/2024 | |
| 2 | | 18 in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA214836 | 03/21/2024 | |

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

Revised: 3/2024

United Natural Foods, Inc. dba UNFI