

ARTHRITEN INFLAMMATORY PAIN FORMULA- acetaminophen, aspirin, caffeine tablet, film coated

Alva-Amco Pharmacal Companies, Inc.

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.

Arthriten Inflammatory Pain Formula

Active ingredients (in each caplet)

Acetaminophen, 250 mg

Aspirin, 250 mg (NSAID)*

Caffeine Anhydrous, 65 mg

*Non-steroidal anti-inflammatory drug

Purpose

Analgesic (pain reliever)

Analgesic (pain reliever)

Pain Reliever Aid

Uses For the temporary relief of minor aches and pains including the minor pain of arthritis.

Warnings

Reye's Syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's Syndrome, a rare but serious illness.

Allergy alert:

Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

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

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

- more than 8 caplets in 24 hours, which is the maximum daily amount for this product.
- with other products containing acetaminophen
- 3 or more alcoholic drinks every day while using this product.

Stomach bleeding warning: This product contains a non-steroidal anti-inflammatory drug (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 (anti-coagulant) 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.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor.

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver disease, liver cirrhosis or kidney disease
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for diabetes, gout or arthritis
- taking any other drug.

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- symptoms do not improve
- pain or fever persists or gets worse
- redness or swelling is present.
- ringing in the ears or hearing loss occurs.
- new symptoms occur
- you experience any of the following signs of stomach bleeding:
 - you feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better

If pregnant or breastfeeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed 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. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- Read all package directions and warnings before use and use only as directed.
- Adults: Two (2) caplets every 6 hours while symptoms persist, not to exceed 4 doses (8 caplets) in 24 hours, or as directed by a doctor.
- Drink a full glass of water with each dose
- Intended for use by normally healthy adults only

- Persons under 18 years of age should use only as directed by a doctor.

Other information

****Contents sealed:** Each Arthriten white colored, capsule shaped caplet bears the identifying mark "ALVA" and a "2" on the reverse side, and is packaged in a bottle with a safety seal under the cap. Do not use if the seal appears broken or if product contents do not match product description. You may report serious side effects to the phone number provided under *Questions?* below.

Inactive ingredients: Hypromellose, maltodextrin, microcrystalline cellulose, polydextrose, polyvinylpyrrolidone, pregelatinized starch, silica, starch, stearic acid, talc, titanium dioxide and triglycerides.

Questions? 1-800-792-2582



Drug Facts

Active ingredients (in each caplet)
 Acetaminophen 250 mg Analgesic (pain reliever)
 Aspirin 250 mg (NSAID)* Analgesic (pain reliever)
 Caffeine Anhydrous 65 mg Pain Reliever Aid
 *Non-steroidal anti-inflammatory drug

Uses For the temporary relief of minor aches and pains including the minor pain of arthritis.

Warnings

Reye's Syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy Alert: Aspirin may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock ■ Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash. If skin reaction occurs, stop use and seek medical help right away.

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

Stomach bleeding warning: This product contains a non-steroidal anti-inflammatory drug (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 non-prescription 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.

Do not use ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer ■ with any other drug

Drug Facts (continued)

Warnings (continued)

containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ■ for more than 10 days for pain unless directed by a doctor ■ for more than 3 days for fever unless directed by a doctor.

Ask a doctor before use if ■ stomach bleeding warning applies to you ■ you have a history of stomach problems, such as heartburn ■ you have high blood pressure, heart disease, liver disease, liver cirrhosis or kidney disease ■ you are taking a diuretic.

Ask a doctor or pharmacist before use if you are ■ taking a prescription drug for diabetes, gout or arthritis ■ taking any other drug.

Stop use and ask a doctor if ■ an allergic reaction occurs. Seek medical help right away. ■ symptoms do not improve ■ pain or fever persists or gets worse ■ redness or swelling is present ■ ringing in the ears or hearing loss occurs ■ new symptoms occur ■ you experience any of the following signs of stomach bleeding: ■ you feel faint ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better.

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed 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. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions ■ Read all package directions and warnings before use. Use only as directed. ■ Adults: Two (2) caplets every 6 hours while symptoms persist, not to exceed 4 doses (8 caplets) in 24 hours, or as directed by a doctor. ■ Drink

Alva
 Divt:
 ALVA-AMCO Pharamcal Cos., Inc.
 Niles, IL 60714, U.S.A. ©2012-2018 ALVA
 ® Reg. U.S. Patent and Trademark Office

Contains no gluten ingredients
 Questions? 1-800-792-2582 www.arthriten.com

Inactive ingredients Hydroxymethylcellulose, maltodextrin, microcrystalline cellulose, polydextrose, polyvinylpyrrolidone, pregelatinized starch, silica, starch, stearic acid, talc, titanium dioxide and trihydroxydes.

Other information ■ CONTENTS SEALED. Each ARTHRITEN white colored, capsule shaped caplet bears the identifying mark "ALVA" and a "2" on the reverse side, and is packaged in a bottle with a safety seal under the cap. Do not use if the seal appears broken or if product contents do not match product description. ■ You may report serious side effects to the phone number provided under Questions? below.

Directions (continued) ■ Intended for use by normally healthy adults only. ■ Persons under 18 years of age should use only as directed by a doctor.

Drug Facts (continued)

37/28-TRQ,
 0518

ARTHRIITEN INFLAMMATORY PAIN FORMULA

acetaminophen, aspirin, caffeine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52389-237
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE (capsule-shaped caplet)	Size	17mm
Flavor		Imprint Code	ALVA;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52389-237-28	1 in 1 CARTON	07/23/2012	
1	NDC:52389-237-01	28 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/23/2012	

Labeler - Alva-Amco Pharmacoal Companies, Inc. (042074856)