

ARTRIFIN 24 CAPLETS- acetaminophen, aspirin, caffeine tablet OPMX LLC

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.

ARTRIFIN

Drug facts

Active ingredient (in each caplet)

Acetaminophen 250 mg

Aspirin 250 mg (NSAID)*

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

Uses

temporarily relieves minor aches and pains due to:

- headache
- a cold
- arthritis
- muscular aches
- sinusitis
- toothache
- premenstrual and menstrual cramps

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
- shock
- facial swelling
- asthma (wheezing)

Liver warning

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

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

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

Caffeine warning

The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness and, occasionally, rapid heartbeat.

Do not use

- if you ever had an allergic reaction to acetaminophen, aspirin, or any other pain reliever/fever reducer
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if

- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis or kidney disease
- you have asthma
- 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 or are under a doctor's care for any serious condition

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
- feel faint
- have bloody or black stools
- vomit blood
- have stomach pain that does not get better
- an allergic reaction occurs.

- Seek medical help right away
- any new symptoms appear
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- painful area is red or swollen

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

Directions

- do not use more than directed
- drink a full glass of water with each dose
- adults and children 12 years and over
 - take 2 tablets every 6 hours
- do not take more than 8 tablets in 24 hours
- children under 12 years: ask a doctor

Other information

- store at 25°C (77°F) excursions permitted between 15-30°C (59-86°F)
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAPS IS BROKEN OR MISSING

Inactive ingredients

corn starch, crospovidone, hypromellose, microcrystalline cellulose, povidone, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

Exclusively distributed by:

OPMX

Chula Vista, CA 91910

PHONE: 619-600-5632

Made for:

inov FARMACEUTIQUE

PRINCIPAL DISPLAY PANEL - 24 CAPLETS

Pain Reliever/Fever Reducer

Mejora los síntomas

Dolores musculares/Muscular Aches

Dolor de Espalda/Backache

Dolor menor de artritis/Minor pain of Arthritis

24 Caplets

NO VARNISH AREA



24 Caplets

ARTRIFIN

Pain Reliever / Fever Reducer
MEJORA LOS SÍNTOMAS

Drug Facts

Active Ingredient
Acetaminophen 250 mg
Aspirin 250 mg (NSAID)
Pain reliever
Pain reliever

Uses
Temporarily relieves minor aches and pains due to:
● headache ● cold ● arthritis ● muscular aches
● sinusitis ● toothache ● premenstrual and menstrual cramps

Warnings
● Allergy alert: Aspirin may cause a severe allergic reaction, which may include a rare but serious illness.
● Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:
● more than 8 tablets in 24 hours, which is the maximum daily amount.
● with other drugs containing acetaminophen.
● 3 or more alcoholic drinks every day while using this product.
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 thinner (anticoagulant) or steroid drug (aspirin, ibuprofen, naproxen, or others).
● have 3 or more alcoholic drinks every day while using this product.
more or for a longer time than directed.

Drug Facts (continued)

Drug Facts (continued)

Do not use ● if you ever had an allergic reaction to acetaminophen, aspirin, or any other pain reliever/fever reducer ● with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if
● you have a history of stomach problems, such as heartburn.
● you have a history of stomach bleeding warning applies to you.

Stop use and ask a doctor if
● you experience any of the following signs of stomach bleeding:
● feel faint ● have blood or black stools ● vomit blood ● have stomach pain that does not get better ● an allergic reaction occurs.
● any new symptoms appear ● ringing in the ears or loss of hearing occurs.
● pain gets worse or lasts for more than 10 days.
● fever gets worse or lasts for more than 3 days.
● painful area is red or swollen.

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

NO VARNISH AREA



Exclusively distributed by:
OPMX
Chula Vista, CA 91910
Phone: 619-600-5632

Made for:
inov
FARMACEUTIQUE

NDC 69729-105-24

ARTRIFIN

Pain Reliever / Fever Reducer



MEJORA LOS SÍNTOMAS



24 Caplets

- * Dolores Musculares / Muscular Aches
- * Dolor de Espalda / Backache
- * Dolor menor de Artritis / Minor pain of Arthritis

Lot. No.:
Exp. Date:

NO VARNISH AREA

NO VARNISH AREA

Drug Facts (continued)

Other Information
● store at 25°C (77°F); excursions permitted between 15°C (59°F) and 30°C (86°F).
● TAMPER EVIDENT DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Inactive Ingredients
● titanium dioxide
● polyethylene glycol, sodium lauryl sulfate, sodium starch glycolate, stearic acid, croscarmellose, hydroxypropylcellulose, polydioxane, polyethylene glycol, croscarmellose, microcrystalline cellulose, povidone.

Drug Facts (continued)

Directions
● do not use more than directed.
● drink a full glass of water with each dose.
● adults and children 17 years and over:
● take 2 tablets every 6 hours.
● do not take more than 8 tablets in 24 hours.
● children under 17 years: ask a doctor.

ARTRIFIN 24 CAPLETS

acetaminophen, aspirin, caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-105
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE B (UNII: SP4S77AH06)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	S53
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-105-24	2 in 1 BOX	09/08/2022	
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 not
final

part343

09/08/2022

Labeler - OPMX LLC (029918743)

Revised: 4/2023

OPMX LLC