

AGRIFEN- acetaminophen, aspirin, caffeine tablet
OPMX LLC

AGRIFEN

Drug facts

Active ingredients
(in each caplets)

Acetaminophen 250 mg
Aspirin 250 mg (NSAID)*
Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

Acetaminophen 250 mgPain reliever
Aspirin 250 mg (NSAID)*.....Pain reliever
Caffeine 65 mg.....Pain reliever aid

*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 CAP 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

Read & Keep Outer Carton for Complete Product Information

PRINCIPAL DISPLAY PANEL - 12 Caplets

NDC 69729-159-12

AGRIFEN

Acetaminophen 250 mg Aspirin 250 mg (NSAID)* Caffeine 65 mg

Desinflama y alivia el dolor de: Fiebre-Cabeza-Dental

Relief inflammation and pains of: Fever-Headache-Toothache

12 Caplets

Head & Keep Outer Carton for Complete Product Information
 INSTRUCCIONES EN ESPAÑOL EN EL INTERIOR DE LA CAYA.

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 CAP IS BROKEN OR MISSING

Inactive Ingredients corn starch, croscollon, hypromellose, microcrystalline cellulose, polydioxanone, polyethylene glycol, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

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

Keep out of reach of children.
 In case of overdose, get medical help or contact 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.

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.
 ■ avoid alcohol while using this product.
 ■ avoid grapefruit and grapefruit juice while using this product.

Stop use and ask a doctor if ■ you experience any of the following signs of stomach bleeding:
 ■ vomit blood ■ have bloody or black stools
 ■ 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

Ask a doctor before use if ■ you have liver disease ■ stomach bleeding ■ 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 under a doctor's care for any serious condition

Drug Facts

Active ingredient (in each caplet)
 Acetaminophen 250 mg
 Aspirin 250 mg (NSAID)*
 Caffeine 65 mg
 Pain reliever
 Pain reliever

Uses ■ temporarily relieves minor aches and pains due to:
 ■ headache ■ a cold ■ arthritis ■ muscular aches ■ sinusitis
 ■ toothache ■ menstrual and menstrual cramps

Warnings ■ **Key symptoms:** 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
 ■ **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 ■ have 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.

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Desinflama y alivia el dolor de:
Fiebre-Cabeza-Dental
 Relief inflammation and pains of:
Fever-Headache-Toothache



12 Caplets

Rev. 01/2024
 Item # INX054
 8 10053 18144 7



AGRIFEN

acetaminophen, aspirin, caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-159
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
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE B (UNII: SP4S77AH06)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSPVIDONE (UNII: 2S7830E561)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE (Capsule shape)	Size	17mm
Flavor		Imprint Code	S53
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-159-12	1 in 1 CARTON	01/26/2024	
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	M013	01/26/2024	

Labeler - OPMX LLC (029918743)

Revised: 1/2024

OPMX LLC