

ANACIN ES- aspirin and caffeine tablet, coated
Insight Pharmaceuticals

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.

ANACIN®

Drug Facts

Active ingredients (per tablet)

Aspirin (NSAID)¹ 500 mg

Caffeine 32 mg

¹ nonsteroidal anti-inflammatory drug

Purposes

Pain reliever

Pain reliever aid

Uses

temporarily relieves minor aches and pains due to:

- headache
- a cold
- muscular aches
- arthritis
- toothache
- 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
- facial swelling
- asthma (wheezing)
- shock

Stomach bleeding warning

This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause 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
- take other drugs containing an NSAID (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

Ask a doctor before use if you have

- asthma
- ulcers
- bleeding problems
- stomach problems that last or come back, such as heartburn, upset stomach, or stomach pain
- high blood pressure
- heart or kidney disease
- taken a diuretic
- reached age 60 or older

Ask a doctor or pharmacist before use if you are

- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug
- taking a prescription drug for diabetes, gout, or arthritis

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- new symptoms occur
- you feel faint, vomit blood, or have bloody or black stools. These are signs of stomach bleeding.
- stomach pain or upset gets worse or lasts
- ringing in the ears or loss of hearing occurs
- painful area is red or swollen
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days

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 heart beat.

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.

Overdose warning

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not use more than directed (see overdose warning)
- drink a full glass of water with each dose
- adults and children 12 years of age and over: take 2 tablets every 6 hours; not more than 8 tablets in 24 hours, or as directed by a doctor
- children under 12 years: ask a doctor

Other information

Keep carton for full drug facts. Read all warnings and directions before use. Store at 20° – 25°C (68° – 77°F). Protect from moisture.

Inactive ingredients

corn starch, hypromellose, microcrystalline cellulose, polyethylene glycol, sodium lauryl sulfate

Distr. by: **INSIGHT Pharmaceuticals Corp.**
Langhorne, PA 19047-1749

Questions?

Call 1-800-344-7239 or visit our website at www.anacin.com

PRINCIPAL DISPLAY PANEL - 75 Tablet Bottle Carton

Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.

ANACIN®

ASPIRIN + CAFFEINE = FAST PAIN RELIEF

Pain Reliever (NSAID) + Pain Reliever Aid

MAX STRENGTH

75

COATED

TABLETS

SEE NEW WARNINGS INFORMATION



ANACIN ES aspirin and caffeine tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-211
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Aspirin (UNII: R16CO5Y76E) (Aspirin - UNII:R16CO5Y76E)	Aspirin	500 mg
Caffeine (UNII: 3G6A5W338E) (Caffeine - UNII:3G6A5W338E)	Caffeine	32 mg

Inactive Ingredients

Ingredient Name	Strength
starch, corn (UNII: O8232NY3SJ)	
hypromelloses (UNII: 3NXW29V3WO)	
cellulose, microcrystalline (UNII: OP1R32D61U)	
polyethylene glycol (UNII: 3WJQ0SDW1A)	
sodium lauryl sulfate (UNII: 368GB5141J)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-211-40	1 in 1 BOX		
1		40 in 1 BOTTLE		
2	NDC:63736-211-75	1 in 1 BOX		
2		75 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/07/2009	

Labeler - Insight Pharmaceuticals (176792315)

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Insight Pharmaceuticals