

ANACIN- aspirin and caffeine tablet
Insight Pharmaceuticals 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.

Anacin - 63736-200

ANACIN- aspirin and caffeine tablet Insight Pharmaceuticals

ANACIN®

Drug Facts

Active ingredients (per tablet)

Aspirin (NSAID)* 400 mg

Caffeine 32 mg

* nonsteroidal anti- inflammatory drug

Purposes

Pain reliever

Pain reliever aid

Uses

temporarily relieves minor aches and pains due to

- Headache
- toothache
- muscular aches
- a cold
- backache
- arthritis
- 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 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
- 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

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 cirrhosis, or kidney disease you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if

you are 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.
- 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
- new symptoms occur
- ringing in the ears or loss of hearing occurs
- redness or swelling is present
- 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 older: take 2 tablets every 6 hours; not more than 8 tablets in 24 hours, or as directed by a doctor
- children under 12 years of age: do not use

Other information

Keep carton for full drug facts and warnings.

Store at 15 – 25°C (59– 77°F). Protect from moisture.

Inactive ingredients

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

Questions?

1-800-344-7239 anacin.com

PRINCIPAL DISPLAY PANEL

ANACIN®

Aspirin (NSAID) Pain Reliever / Caffeine Pain Reliever Aid

100 COATED TABLETS

TRUSTED • SAFE • EFFECTIVE | 100 COATED TABLETS

Actual Size

#FEEL BETTER FAST

ASPIRIN + CAFFEINE = FAST PAIN RELIEF

ANACIN

Aspirin (NSAID) Pain Reliever / Caffeine Pain Reliever Aid

ASPIRIN + CAFFEINE = FAST PAIN RELIEF

ASPIRIN + CAFFEINE = FAST PAIN RELIEF

100 COATED TABLETS

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

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are taking a prescription drug for: diabetes • gout • arthritis

Stop use and ask a doctor if: • an allergic reaction occurs. Seek medical help right away. • 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 • **new symptoms occur** • ringing in the ears or loss of hearing occurs • **redness or swelling is present** • **pain gets worse or lasts more than 10 days** • **fever gets worse or lasts more than 3 days**. These may be signs of a serious condition.

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.

Directions

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

Other information Store at 15° – 25°C (59° – 77°F). Protect from moisture.

Inactive ingredients corn starch, croscarmellose sodium, hypromellose, mineral oil, silicon dioxide, sodium lauryl sulfate, stearic acid, talc, titanium dioxide, triacetin

Questions? 1-800-344-7239 anacin.com

Keep carton for future reference.

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Drug Facts

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Aspirin (NSAID)* 400 mgPain reliever
Caffeine 32 mgPain reliever aid
* nonsteroidal anti-inflammatory drug	

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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.

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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 • 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: This product contains caffeine. 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.

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

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 cirrhosis, or kidney disease • you are taking a diuretic • you have asthma

ANACIN

asprin and caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-200
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	400 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	32 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OPIR32D61U)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-200-04	1 in 1 BOX	06/25/2009	06/30/2023
1		4 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63736-200-93	1 in 1 BOX	06/25/2009	
2		300 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:63736-200-30	1 in 1 BOX	06/25/2009	06/30/2023
3		30 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:63736-200-50	1 in 1 BOX	06/25/2009	
4		50 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:63736-200-90	1 in 1 BOX	06/25/2009	
5		100 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:63736-200-91	1 in 1 BOX	06/25/2009	06/30/2023
6		130 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:63736-200-92	125 in 1 BOX	06/25/2009	
7		1 in 1 POUCH; Type 0: Not a Combination Product		
8	NDC:63736-200-95	750 in 1 BOX	06/25/2009	06/30/2023
8		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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Labeler - Insight Pharmaceuticals LLC (055665422)

Revised: 7/2020

Insight Pharmaceuticals LLC