

ACETAMINOPHEN ASPIRIN AND CAFFEINE - acetaminophen, aspirin and caffeine tablet, film coated
Aurohealth LLC

Acetaminophen, Aspirin (NSAID) and Caffeine Tablets USP

Drug Facts

Active ingredients (in each tablet)

Acetaminophen USP 250 mg

Aspirin USP 250 mg (NSAID*)

Caffeine USP 65 mg

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever

Pain reliever

Pain reliever aid

Use

treats migraine

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: Acetaminophen may cause severe skin reactions. Symptoms may include: • skin reddening • blisters • rash. If a skin reaction occurs, stop use and seek medical help right away.

Allergy alert: Aspirin may cause a severe allergic reaction which may include: • hives • facial swelling • asthma (wheezing) • shock.

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

- more than 2 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

Medication overuse headache warning: Headaches may worsen if this product is used for 10 or more days per month.

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.

Do not use

- if you have 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 never had migraines diagnosed by a health professional
- you have a headache that is different from your usual migraines
- you have the worst headache of your life
- you have fever and stiff neck
- you have headaches beginning after or caused by head injury, exertion, coughing or bending
- you experienced your first headache after the age of 50
- you have daily headaches
- you have a migraine so severe as to require bed rest
- 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 are taking a diuretic
- you have asthma
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have vomiting with your migraine headache

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for: • diabetes • gout • arthritis
- under a doctor's care for any serious condition
- taking any other drug
- taking any other product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer

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
- have stomach pain that does not get better
- your migraine is not relieved or worsens after first dose
- new or unexpected symptoms occur
- ringing in the ears or loss of hearing occurs

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use aspirin at 20 weeks or later in 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 right away (1-800-222-1222). 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**
- adults: take 2 tablets with a glass of water
- if symptoms persist or worsen, ask your doctor
- do not take more than 2 tablets in 24 hours, unless directed by a doctor
- under 18 years of age: ask a doctor

Other information

- store at controlled room temperature 20°-25°C (68°-77°F)
- close cap tightly after use

- read all product information before using. Keep this box for important information.

Inactive ingredients

crospovidone, glyceryl monostearate, low-substituted hydroxypropyl cellulose, microcrystalline cellulose, polyvinyl alcohol, povidone, pregelatinized starch (maize), sodium lauryl sulfate, stearic acid, talc and titanium dioxide.

Questions or comments?

call **1-855-274-4122** (Monday – Friday 8:30 AM to 5:00 PM EST)

Distributed by:

AUROHEALTH LLC

279 Princeton-Hightstown Road,
East Windsor, NJ 08520

Made in India

Code: AP/DRUGS/04/2016

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 250 mg/250 mg/65 mg Container Label - 8 Tablets

NDC 58602-883-34 Primary Health

****COMPARE TO Excedrin®
Migraine active ingredients***

**Acetaminophen,
Aspirin (NSAID)
and Caffeine Tablets USP
250 mg/250 mg/65 mg**

Pain Reliever/Pain Reliever Aid

200 Tablets

FRONT

NDC 51602-883-34

PH PrimaryHealth

Do not use if seal imprinted with SEALED for YOUR PROTECTION under the bottle cap is broken or missing.

Lift Here for **Drug Facts** ▶

“COMPARE TO Excedrin®
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Aspirin (NSAID)
and Caffeine Tablets USP
250 mg/250 mg/65 mg**

Pain Reliever/Pain Reliever Aid

200 Tablets

READ ALL PRODUCT INFORMATION BEFORE USING. KEEP BOX FOR IMPORTANT INFORMATION.

Distributed by:
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279 Princeton-Hightstown Road,
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LM-4949 P1430812



Drug Facts

Active Ingredients (in each tablet) **Purposes**
Acetaminophen USP 250 mg.....Pain reliever
Aspirin USP 250 mg (NSAID)*.....Pain reliever
Caffeine USP 65 mg.....Pain reliever aid
*nonsteroidal anti-inflammatory drug

Use ■ treats migraine

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

Drug Facts (continued)

early sign of Reye's syndrome, a rare but serious illness.
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Allergy alert: Aspirin may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock.
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 2 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.

BACK 1

Drug Facts (continued)

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■ with any other drug containing acetaminophen (prescription or nonprescription).
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Drug Facts (continued)

Ask a doctor before use if ■ you have never had migraines diagnosed by a health professional ■ you have a headache that is different from your usual migraines ■ you have the worst headache of your life ■ you have fever and stiff neck ■ you have headaches beginning after or caused by head injury, exertion, coughing or bending ■ you experienced your first headache after the age of 50 ■ you have daily headaches ■ you have a migraine so severe as to require bed rest ■ 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 are taking a diuretic ■ you have asthma ■ you have problems or serious side effects from taking pain relievers or fever reducers ■ you have vomiting with your migraine headache.

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■ taking a prescription drug for: ■ diabetes ■ gout ■ arthritis ■ under a doctor's care for any serious condition ■ taking any other drug ■ taking any other product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer.

Stop use and ask a doctor if ■ an allergic reaction occurs. Seek medical help right away.

P1430812
LM-4949

BACK 2

Drug Facts (continued)

■ 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
■ your migraine is not relieved or worsens after first dose ■ new or unexpected symptoms occur ■ ringing in the ears or loss of hearing occurs.

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

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Drug Facts (continued)

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Inactive Ingredients crospravdone, glyceryl monostearate, low-substituted hydroxypropyl cellulose, microcrystalline cellulose, polyvinyl alcohol, povidone, pregelatinized starch (maize), sodium lauryl sulfate, stearic acid, talc and titanium dioxide

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**This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare., distributor of Excedrin® Migraine

LM-4949
P1430812

ACETAMINOPHEN ASPIRIN AND CAFFEINE

acetaminophen, aspirin and caffeine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-883
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CROSPVIDONE (120 .MU.M) (UNII: 68401960MK)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 2165RE0K14)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE K30 (UNII: U725QWY32X)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (White to off-White)	Score	no score
Shape	CAPSULE (biconvex)	Size	18mm
Flavor		Imprint Code	T;57
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-883-34	200 in 1 BOTTLE; Type 0: Not a Combination Product	08/30/2022	
2	NDC:58602-883-38	300 in 1 BOTTLE; Type 0: Not a Combination Product	08/30/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211695	08/30/2022	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(58602-883) , MANUFACTURE(58602-883)

Revised: 8/2022

Aurohealth LLC