

EXTRA PAIN RELIEF- acetaminophen, aspirin and caffeine tablet, film coated
Apace Packaging, 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.

Acetaminophen, Aspirin (NSAID) and Caffeine (Product contract packaged by Apace Packaging, LLC)

ACTIVE INGREDIENTS

ACETAMINOPHEN 250 MG

ASPIRIN 250 MG (nsaid*)

CAFFEINE 65 MG

* NONSTEROIDAL ANIT-INFLAMMATORY DRUG

INACTIVE INGREDIENTS

Carnauba Wax, Colloidal Silicon Dioxide, Hypromellose, Microcrystalline Cellulose, Mineral Oil, Povidone, Pregelatinized Starch, Sodium Starch Gylolate, Stearic Acid, Titanium Dioxide

PAIN RELIEVER - PAIN RELIEVER AID

DIRECTIOINS

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, NOT MORE THAN 8 TABLETS IN 24 HOURS .

USES

TEMPORARILY RELIEVES MINOR ACHES AND PAINS DUE TO: headache - a cold - arthritis - muscular aches - toothache - premenstrual and menstrual cramps

Do not use if you have ever had an allergic reaction to acetaminophe, 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.

WARNINGS

REYE'S SYNDROME:

Children and teenages 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 eary sign of Reye's syndrome, a rare but serious illnes.

ALLERY ALERT

Aspirin may cause a severe allergic reaction which may include:
hives

facial swelling

asthma (sheezing)

shock

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 usng 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 (anticogulant) or steroid drug

take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen,naproxen, or others)

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 which while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness and occasionally, rapid heart beat.

In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any sighs or symptoms

If Pregnant or breast-feeding ask a helth 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 prombles inthe unborn child or complications during delivery.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 50268-053-15

EXTRA PAIN RELIEF

Acetaminophen, Aspirin (NSAID) and Caffeine

EXTRA STREGTH

50 Tablets (5 X 10) Unit Dose

5026805315

NDC 50268-053-15

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Drug Facts

Active ingredients (in each tablet)	Purpose
Acetaminophen 250 mg	Pain 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

Mfg. Rev. 02/16

AV 08/16 (P)



Peel Here

Drug Facts (continued)

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 or 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 • shock • 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 are taking a diuretic • you have asthma



Drug Facts (continued)

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 • 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. • ringing in the ears or loss of hearing occurs • painful area is red or swollen • pain gets worse or lasts for more than 3 days • any new symptoms appear

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 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; not 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)
• use by expiration date on package

Inactive ingredients carnauba wax, colloidal silicon dioxide, hypromellose, microcrystalline cellulose, mineral oil, pregelatinized starch, povidone, sodium starch glycolate, stearic acid, titanium dioxide

Manufactured for:
AvKARE, Inc.
Pulaski, TN 38478

Mfg. Rev. 02/16

AV 08/16 (P)

EXTRA PAIN RELIEF

acetaminophen, aspirin and caffeine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:15338-703(NDC:49483-370)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE (CAPSULE SHAPED TABLET)	Size	18mm
Flavor		Imprint Code	TCL370
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15338-703-05	50 in 1 BOX, UNIT-DOSE	08/23/2016	
1	NDC:15338-703-11	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

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AVKARE

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/23/2016	

Labeler - Apace Packaging, LLC (361961142)

Establishment

Name	Address	ID/FEI	Business Operations
Time Cap Laboratories, Inc.		037052099	manufacture(15338-703)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 11/2018

Apac Packaging, LLC