

ANA-DENT- acetaminophen, aspirin, caffeine tablet
Belmora 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.

Ana-Dent 44-571

Active ingredients (in each gelcap)

Acetaminophen 250 mg

Aspirin 250 mg (NSAID)*

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Pain reliever

Pain reliever aid

Uses

- temporarily relieves minor aches and pains due to:
 - a cold
 - headache
 - arthritis
 - muscular aches
 - 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:

- shock
- facial swelling
- hives
- asthma (wheezing)

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.

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

- more than 4,000 mg of acetaminophen in 24 hours

- 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

- have had stomach ulcers or bleeding problems
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older
- 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 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have liver disease
- you have asthma
- you have a history of stomach problems, such as heartburn
- you are taking a diuretic
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease

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

- 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
- ringing in the ears or a loss of hearing occurs
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- redness or swelling is present
- new symptoms occur

These could 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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

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

Other information

- avoid high humidity
- see end flap for expiration date and lot number
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients

corn starch, D&C yellow #10, FD&C blue #1, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, propylene glycol, shellac glaze, simethicone, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

Call 1-888-779-2877 M-F 9AM-5PM EST

Principal display panel

Belmora LLC

NDC 27854-175-01

ANA-DENT

Extra Strength

Headache Relief

24 Gelcaps

Actual Size

Ingredients for strong relief!

Acetaminophen 250 mg

Aspirin (NSAID) 250 mg

Caffeine 65 mg

Pain Reliever

Pain Reliever Aid

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

Distributed by Belmora LLC, 2011 Crystal Dr. #400, Arlington, VA 22202 www.anadentusa.com

Distributed by Belmora LLC, 2231 Crystal Dr.,
Suite 400, Arlington, VA 22202
www.anadentusa.com

INGREDIENTES ACTIVOS
 Propósito
 (en cada capsula)
 Acetaminofeno 250 mg
 Aspirina 250 mg (ASA)
 Anestésico
 Aída analgésica
 Colerina 65 mg
 Medicamentos antiinflamatorios no esteroides

USOS: Alivia importantes dolores y síntomas similares a la gripe no deben usar este producto, al usar este producto, si ocurren cambios en el comportamiento con náuseas y vómitos, consulte a un médico porque estos síntomas pueden ser una señal temprana del síndrome de Reye, una enfermedad poco común, pero grave. La aspirina puede causar una reacción alérgica severa, que puede incluir:
 ■ convulsión ■ hinchazón facial ■ urticaria ■ asma (estrictos)

Alerta sobre alergia: El acetaminofeno puede provocar reacciones alérgicas severas. Los síntomas pueden incluir: ■ enrojecimiento de la piel ■ ampollas ■ erupción

Advertencia sobre el hígado: Este producto contiene acetaminofeno. Dicho ingrediente severo puede causar si usted toma más de 4000 mg de acetaminofeno en 24 horas.

Advertencias:
 Vea el cartón para las advertencias completas
 ■ alérgico ■ calambos musculares y mialgias
 ■ dolores musculares ■ erizado ■ eritema
 ■ molestias leves debidas ■ estado de alerta

Advertencias:
 No use el producto:
 ■ si alguna vez ha tenido una reacción alérgica al acetaminofeno, aspirina o cualquier otro medicamento que contenga acetaminofeno (por receta o sin receta). Si no está seguro de si un medicamento que contenga acetaminofeno es un medicamento que contenga acetaminofeno, pregúntele a un médico o farmacéutico. ■ si alguna vez ha tenido una reacción alérgica a este producto o a cualquiera de sus ingredientes

Alerta sobre cafeína:
 La dosis recomendada de este producto contiene tanta cafeína como una taza de café. Limite el consumo de medicamentos, alimentos o bebidas que contengan cafeína mientras toma este producto porque demasiada cafeína puede causar nerviosismo, irritabilidad, insomnio, y ocasionalmente, latidos que se indican

Alerta sobre saqueo estomacal:
 Este producto contiene un MAHE que puede causar graves hemorragias estomacales.
 ■ otros medicamentos que contengan acetaminofeno ■ 3 o más tragos alcohólicos cada día mientras usa este producto

La posibilidad es mayor si usted:
 ■ ha tenido úlceras estomacales o problemas de sangrado ■ toma anticoagulantes o esteroides ■ toma otros medicamentos que contengan medicamentos antiinflamatorios no esteroides (MAHE) con receta o sin receta médica (aspirina, ibuprofeno, naproxeno, u otros) ■ toma 3 o más tragos alcohólicos cada día mientras usa este producto ■ tiene 65 años o más ■ toma una dosis mayor del medicamento o por más tiempo que el indicado

INFORMACION SOBRE EL MEDICAMENTO

LEVANTE AQUI PARA OBTENER INFORMACION SOBRE HECHOS DE DROGAS EN ESPAÑOL

Drug Facts (continued)

Active Ingredients (in each gelcap): Purpose
 Acetaminophen 250 mg
 Aspirin 250 mg (ASA)
 Pan relever
 Pan relever
 Caffeine 65 mg
 nonsteroidal anti-inflammatory drug

Uses
 ■ temporarily relieves minor aches and pains due to: ■ cold ■ headache ■ arthritis ■ muscle aches ■ toothache

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: ■ shock ■ facial swelling ■ hives ■ asthma (wheezing)
 Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:
 ■ skin redness ■ blisters ■ rash
 ■ a skin reaction occurs, stop use and seek medical help right away.
 Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 4,000 mg of acetaminophen in 24 hours ■ 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 ■ have had stomach ulcers or bleeding problems ■ take other drugs containing prescription or over-the-counter NSAIDs, which may cause severe stomach bleeding.

Do not use ■ if you have ever had an allergic reaction to acetaminophen, aspirin, or any other pain reliever/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. ■ if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if: ■ stomach bleeding warning applies to you ■ you have liver disease ■ you have asthma ■ you have a history of stomach problems, such as heartburn ■ you are taking a diuretic ■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease

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: ■ an allergic reaction occurs. Seek medical help right away. ■ you experience any of the following signs of stomach bleeding: ■ hot/flat

Drug Facts (continued)
 ■ stomach bleeding ■ hot/flat ■ you experience any of the following signs of stomach bleeding: ■ hot/flat

Do not use ■ if you have ever had an allergic reaction to acetaminophen, aspirin, or any other pain reliever/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. ■ if you have ever had an allergic reaction to this product or any of its ingredients

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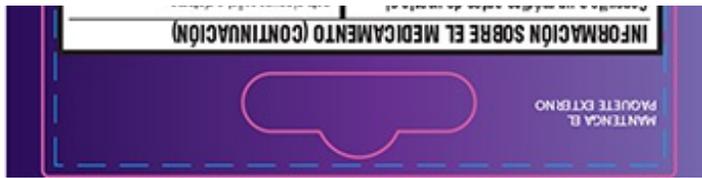
Stop use and ask a doctor if: ■ an allergic reaction occurs. Seek medical help right away. ■ you experience any of the following signs of stomach bleeding: ■ hot/flat

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

101-175-27854-DNC



ANA-DENT



Ana-Dent 44-571

ANA-DENT

acetaminophen, aspirin, caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:27854-175
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
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	GREEN	Score	no score
Shape	OVAL	Size	20 mm
Flavor		Imprint Code	L;1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27854-175-01	1 in 1 CARTON	09/10/2019	
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	09/10/2019	

Labeler - Belmora LLC (112753244)**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(27854-175)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(27854-175)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(27854-175)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(27854-175)

Revised: 8/2019

Belmora LLC