

**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.*

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**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](http://www.anadentusa.com)

Distributed by Belmora LLC, 2231 Crystal Dr.,  
Suite 400, Arlington, VA 22202  
[www.anadentusa.com](http://www.anadentusa.com)



Fuerza Extra/Extra Strength

# Cefalea Aliviar/ Headache Relief

 **24 Cápsulas  
Gelcaps**  
Actual Size/Tamaño Real



## Ingredientes para un fuerte alivio! Ingredients for strong relief!

**Acetaminofeno/Acetaminophen 250 mg**  
**Aspirina (AINE)/Aspirin (NSAID) 250 mg**  
**Cafeína/Caffeine 65 mg**

Analgésico/Pain Reliever  
Ayuda Analgésica/Pain Reliever Aid



NO PRINT

NO PRINT

# ANA-DENT

## Cefalea Aliviar/ Headache Relief

**Acetaminofeno/Acetaminophen,  
Aspirina (AINE)/Aspirin (NSAID),  
Cafeína/Caffeine**

**24 Cápsulas  
Gelcaps** Analgésico/Pain Reliever  
Ayuda Analgésica/Pain Reliever Aid



GLUE AREA  
NO PRINT

GLUE AREA  
NO PRINT  
Z FOLD  
C8788

**Drug Facts (continued)**

- vomit blood ■ have blood 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 prescribed 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 right away. See the inside of this cap for important information about this medicine and its use.

**Drug Facts (continued)**

Poison Control Center (1-800-222-1222) night or after hours call (800) 555-1222. If you do not have a doctor, call for advice about this medicine.

**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 6 gelcaps in 24 hours
- children under 12 years: ask a doctor.

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

B-0098-571-08  
ORIG061857108

**Deje de tomarlo y consulte a un médico si:**

- se produce una reacción alérgica. Busque ayuda médica de inmediato. ■ opertencia cualquiera de los siguientes: vómitos de sangre, migraña o con sangre
- se siente débil ■ tiene heces negras o con sangre
- vomita sangre ■ tiene dolor de estómago que no mejora ■ siente zumbidos en los oídos o tiene pitido de la audición ■ el dolor empeora o dura más de 3 días ■ la fiebre empeora o dura más de 3 días ■ el embotamiento o hinchazón están presentes ■ aparecen nuevos síntomas

Este producto puede ser sellado de una alcohol ginebra.

**Si está embarazada o en período de lactancia,** pínguese en contacto con un Centro de Control de Enfermedades (1-800-222-1222) de inmediato. La atención médica oportuna es fundamental para los adultos, así como para los niños, incluso si usted no

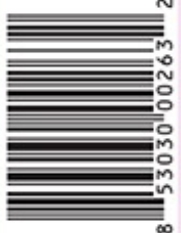
**¿PREGUNTAS Y COMENTARIOS?**  
1-888-779-2877 L-V 9AM-5PM EST

**Otra información:** EVIDENCIA DE MANIPULACIÓN: NO USAR SI EL SELLO DE SEGURIDAD IMPRESO BAJO LA TAPA ESTÁ ROTO O FALTANTE

almacenar a 25°C (77°F); excursiones permitidas entre 15°-30°C (59°-86°F) ■ ver la fecha de caducidad y el número de lote ■ evitar humedad alta ■ guardar en su empaque original ■ mantener fuera del alcance de los niños ■ mantener en su empaque original ■ guardar en su empaque original ■ mantener en su empaque original

**Ingredientes:** Inactive ingredients: acetaminophen, aspirin, caffeine, hydroxypropyl cellulose, hypromellose, polyethylene glycol, croscarmellose, polyethylene glycol, croscarmellose, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

**Questions or comments?**  
Call 1-888-779-2877 M-F 9AM-5PM EST



No print/No varnish  
Lot & Exp date

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

**Drug Facts (continued)**

**Inactive ingredients:** acetaminophen, aspirin, caffeine, hydroxypropyl cellulose, hypromellose, polyethylene glycol, croscarmellose, polyethylene glycol, croscarmellose, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

**Questions or comments?**  
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www.watkinslab.com  
EVIDENTE DE TAMPERO



Ana-Dent 44-571

## ANA-DENT

acetaminophen, aspirin, caffeine tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:27854-175
<b>Route of Administration</b>	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

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

**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