

ANA-DENT PAIN RELIEF- naproxen sodium tablet, film coated
Belmora LLC

Ana-Dent PAIN RELIEF

Drug Facts

Active ingredient (in each tablet)

Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/ fever reducer

Uses ■ temporarily relieves minor aches and pain due to: ■ headache ■ muscular aches ■ toothache ■ the common cold ■ backache ■ menstrual cramps ■ minor pain of arthritis

■ temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: ■ shock ■ facial swelling ■ asthma (wheezing) ■ hives ■ skin reddening ■ blisters ■ rash

If an allergic reaction occurs, stop use and seek medical help right away.

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 blood thinning (anticoagulant) or steroid drug

■ are age 60 or older

■ take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]

■ take more or for a longer time than directed

■ have 3 or more alcoholic drinks every day while using this product.

Do not use ■ right before or after heart surgery ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer

Ask a doctor before use if

■ the stomach bleeding warning applies to you

■ you have a history of stomach problems, such as heartburn

■ you have asthma

■ you have high blood pressure, heart disease, liver cirrhosis or kidney disease

■ you have a problems or serious side effects from taking pain relievers or fever reducers

- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

- 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
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium 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 ■ do not take more than directed

■ the smallest effective dose should be used

- drink a full glass of water with each dose
- adults and children 12 years and older
 - take 1 tablet every 8 to 12 hours while symptoms last
 - for the first dose, you may take 2 tablets within the first hour
 - do not exceed 2 tablets in any 8-to 12-hour period
 - do not exceed 3 tablets in a 24-hour period
- children under 12 years: ask a doctor

Other information

- **each tablet contains:** sodium 20 mg
- store at 20°-25°C (68°-77°F). Avoid high humidity and excessive heat above 40°C (104°F)
- see end flap for expiration date and lot number

Inactive ingredients colloidal silicon dioxide, FD & C Blue#2 Aluminum Lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide, talc

Questions or comments?

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

For toothaches

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Distributed by Belmora LLC, 2011 Crystal Dr. Suite 400 Arlington, VA 22202

www.anadentusa.com

Made in India

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

Packaging

Indicaciones de uso:

- Para el dolor de cabeza, migraña, resaca de alcohol, dolor de muelas, dolor de garganta, dolor de oídos, dolor de ojos, dolor de nariz, dolor de espalda, dolor de cuello, dolor de hombros, dolor de codos, dolor de muñecas, dolor de manos, dolor de pies, dolor de tobillos, dolor de rodillas, dolor de caderas, dolor de brazos, dolor de piernas, dolor de espalda baja, dolor de espalda alta, dolor de cuello, dolor de cabeza, dolor de ojos, dolor de nariz, dolor de garganta, dolor de oídos, dolor de muelas, dolor de dientes, dolor de encías, dolor de labios, dolor de boca, dolor de piel, dolor de uñas, dolor de pelo, dolor de cuero cabelludo, dolor de ojos, dolor de nariz, dolor de garganta, dolor de oídos, dolor de muelas, dolor de dientes, dolor de encías, dolor de labios, dolor de boca, dolor de piel, dolor de uñas, dolor de pelo, dolor de cuero cabelludo.

Contraindicaciones:

- No se debe utilizar si se tiene antecedentes de úlceras gástricas o intestinales, insuficiencia renal o hepática, hipertensión arterial, enfermedad cardíaca, asma, diabetes, trastornos de la coagulación, embarazo o lactancia.

Precauciones:

- Evitar el consumo de alcohol durante el tratamiento.
- Evitar la exposición prolongada al sol.
- Evitar la conducción de vehículos o el uso de maquinaria pesada si se experimenta somnolencia o mareos.

Efectos secundarios:

- Dolor de estómago, náusea, vómito, diarrea, estreñimiento, dolor de cabeza, mareos, somnolencia, dolor de garganta, dolor de oídos, dolor de muelas, dolor de dientes, dolor de encías, dolor de labios, dolor de boca, dolor de piel, dolor de uñas, dolor de pelo, dolor de cuero cabelludo.

Interacciones:

- Evitar el uso simultáneo con otros medicamentos que contengan Naproxeno.
- Evitar el uso simultáneo con medicamentos que contengan salicilatos.

Información sobre el medicamento (continuación)

Ano-Dent
ALIVIA EL DOLOR
PAIN RELIEF

Naproxen Sodium Tablets, 220 mg
Naproxeno Sódico Tablet, 220 mg

**PAIN RELIEVER/
FEVER REDUCER
(NSAID)**

**ANALGÉSICO/
BAJA LA FIEBRE
(AINE)**

24 TABLETS / TABLETAS

Keep and read outer package for complete product information (continued)

Indicaciones de uso:

- Para el dolor de cabeza, migraña, resaca de alcohol, dolor de muelas, dolor de garganta, dolor de oídos, dolor de ojos, dolor de nariz, dolor de espalda, dolor de cuello, dolor de hombros, dolor de codos, dolor de muñecas, dolor de manos, dolor de pies, dolor de tobillos, dolor de rodillas, dolor de caderas, dolor de brazos, dolor de piernas, dolor de espalda baja, dolor de espalda alta, dolor de cuello, dolor de cabeza, dolor de ojos, dolor de nariz, dolor de garganta, dolor de oídos, dolor de muelas, dolor de dientes, dolor de encías, dolor de labios, dolor de boca, dolor de piel, dolor de uñas, dolor de pelo, dolor de cuero cabelludo.

Contraindicaciones:

- No se debe utilizar si se tiene antecedentes de úlceras gástricas o intestinales, insuficiencia renal o hepática, hipertensión arterial, enfermedad cardíaca, asma, diabetes, trastornos de la coagulación, embarazo o lactancia.

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ALIVIA EL DOLOR
PAIN RELIEF

**Pain Reliever/
Fever Reducer
ANALGESICO/
BAJA LA FIEBRE**

10-101-95823-DCN



DRUG FACTS LABEL

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)* *nonsteroidal anti-inflammatory drug</p> <p>Purpose Pain reliever/fever reducer</p> <p>Uses</p> <ul style="list-style-type: none"> temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> headache muscular aches toothache the common cold backache menstrual cramps minor pain of arthritis temporarily reduces fever 	<p>Drug Facts (continued)</p> <p>Ask a doctor before use if</p> <ul style="list-style-type: none"> the stomach bleeding warning applies to you you have a history of stomach problems, such as heartburn you have asthma you have high blood pressure, heart disease, liver cirrhosis, or kidney disease you have problems or serious side effects from taking pain relievers or fever reducers you are taking a diuretic <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> under a doctor's care for any serious condition taking any other drug 	<p>Drug Facts (continued)</p> <p>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.</p> <p>Directions</p> <ul style="list-style-type: none"> do not take more than directed the smallest effective dose should be used drink a full glass of water with each dose adults and children 12 years and older <ul style="list-style-type: none"> take 1 tablet every 8 to 12 hours while symptoms last for the first dose you may take 2 tablets within the first hour do not exceed 2 tablets in any 8- to 12-hour period do not exceed 3 tablets in a 24-hour period children under 12 years: ask a doctor 	<p>Drug Facts (continued)</p> <p>Other information</p> <ul style="list-style-type: none"> each tablet contains: sodium 20 mg store at 20°-25°C (68°-77°F). Avoid high humidity and excessive heat above 40°C (104°F) see end flap for expiration date and lot number <p>Inactive ingredients colloidal silicon dioxide, FD & C Blue #2 Aluminum Lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide, talc</p> <p>Questions or comments? Call 1-888-779-2877 M-F 9AM-5PM EST</p>
<p>Warnings</p> <p>Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:</p> <ul style="list-style-type: none"> shock facial swelling asthma (wheezing) hives skin reddening blisters rash <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:</p> <ul style="list-style-type: none"> have had stomach ulcers or bleeding problems take a blood thinning (anticoagulant) or steroid drug are age 60 or older take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) take more or for a longer time than directed have 3 or more alcoholic drinks every day while using this product <p>Do not use</p> <ul style="list-style-type: none"> right before or after heart surgery if you have ever had an allergic reaction to any other pain reliever/fever reducer 	<p>When using this product</p> <ul style="list-style-type: none"> take with food or milk if stomach upset occurs the risk of heart attack or stroke may increase if you use more than directed or for longer than directed <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> you experience any of the following signs of stomach bleeding: <ul style="list-style-type: none"> feel faint vomit blood have bloody or black stools have stomach pain that does not get better pain gets worse or lasts more than 10 days fever gets worse or lasts more than 3 days you have difficulty swallowing it feels like the pill is stuck in your throat redness or swelling is present in the painful area any new symptoms appear <p>If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium 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.</p>		

ANA-DENT PAIN RELIEF

naproxen sodium tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:27854-701
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN	220 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	

POVIDONE K30 (UNII: U725QWY32X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	blue (light blue)	Score	no score
Shape	ROUND (Circular)	Size	10 mm
Flavor		Imprint Code	J;67
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27854-701-01	1 in 1 CARTON	05/15/2020	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205497	05/15/2020	

Labeler - Belmora LLC (112753244)