

BACK AND MUSCLE PAIN- naproxen tablet, coated WALGREENS

BACK AND MUSCLE ALL DAY PAIN RELIEF - Naproxen Sodium Tablets 220 mg

DRUG FACTS

ACTIVE INGREDIENT

Naproxen Sodium 220 mg
(naproxen 200 mg)(NSAID)*
*nonsteroidal anti-inflammatory drug

PURPOSE

Purposes

Pain reliever/ fever reducer

Uses

temporarily relieves minor aches and pain due to:

- minor pain of arthritis
- muscular aches
- backache
- menstrual cramps
- headache
- toothache
- the common cold

temporarily reduces fever

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

asthma (wheezing)

blisters

facial swelling

hives

rash

shock

skin reddening

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:

are age 60 or older

have bad 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.

Heart attack and stroke warning: NSAID's, except aspirin, increases the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

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 high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

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

you have symptoms of heart problems or stroke:

- chest pain
- trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling

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 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.

In case of overdose, get medical help or contact a poison control center 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 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).

INACTIVE INGREDIENTS

Colloidal silicon dioxide, croscarmellose sodium, FD&C blue #2 lake, Hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide.

call **1-877-290-4008**

24 CT

Print & Varnish

Lot No. Exp. Date



6909 REV 02/01

123. ALWAYS KEEP ALIVIN FOR COMPLETE RELIEF OF PAIN AND MUSCLE PAIN.

Drug Facts (continued)

Active ingredient: Naproxen sodium USP, 220 mg (for each tablet). **Purpose:** Pain reliever.

Warnings: Do not take if you are allergic to naproxen sodium or any of the ingredients. Do not take if you are taking other NSAIDs (non-steroidal anti-inflammatory drugs).

Directions: Take 1 tablet every 12 hours with food or after a meal. Do not take more than 2 tablets in 24 hours.

Other information: Keep this and all other medicines out of the reach of children. This medicine may cause drowsiness. Do not drive or operate machinery if you feel drowsy after taking this medicine.

Contains: Contains 24 tablets in a blister pack. Each tablet is white and round with the letters 'W' and 'O' on opposite sides.

How to use: Take 1 tablet every 12 hours with food or after a meal. Do not take more than 2 tablets in 24 hours.

Side effects: Common side effects include heartburn, indigestion, and constipation. Serious side effects include stomach pain, black stools, and blood in stool.

Interactions: Do not take with other NSAIDs, aspirin, or blood thinners. Do not take with alcohol.

Storage: Store at room temperature (20° to 25°C). Keep in original container.

Expiration date: Use by the expiration date on the label.

Lot number: E1385

Manufacturer: Walgreens Varnish Omit

Drug Facts (continued)

Warnings: Do not take if you are allergic to naproxen sodium or any of the ingredients. Do not take if you are taking other NSAIDs (non-steroidal anti-inflammatory drugs).

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Other information: Keep this and all other medicines out of the reach of children. This medicine may cause drowsiness. Do not drive or operate machinery if you feel drowsy after taking this medicine.

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Varnish Omit

NDC 0363-9609-42

NEW

Walgreens All Day Pain Relief

BACK & MUSCLE PAIN

NAPROXEN SODIUM TABLETS USP, 220 mg / PAIN RELIEVER / FEVER REDUCER (NSAID)

BACK & MUSCLE PAIN 12 HOUR TABLETS

24 TABLETS



ACTUAL SIZE

Varnish Omit E1385

Varnish Omit

OR080114-F2

100 CT

[illegible]

90 CT

NDC 0363-9609-09

Walgreens

BACK & MUSCLE PAIN

All Day Pain Relief

NAPROXEN SODIUM TABLETS USP,
220 mg / PAIN RELIEVER /
FEVER REDUCER (NSAID)

12 Hour

90 TABLETS

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Uses

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

Warnings Allergy alert:

Naproxen sodium may cause a severe
allergic reaction, especially in people allergic to aspirin.
Symptoms may include: ■ hives ■ facial swelling ■ asthma
(wheezing) ■ shock ■ skin reddening ■ rash ■ blisters 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: ■ 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 **Heart attack and stroke warning:** NSAIDs, except
aspirin, increase the risk of heart attack, heart failure, and
stroke. These can be fatal. The risk is higher if you use more
than directed or for longer than directed. If pregnant or
breast-feeding, ask a health professional before use.

Keep out of reach of children.

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

■ TAMPER EVIDENT: DO NOT USE THIS
PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH
OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING
■ 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).

Questions or comments?

call 1-877-290-4008 609F REV 0921
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Lot No.:

Exp. Date:

Varnish

Omit Area



BACK AND MUSCLE PAIN

naproxen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-9609
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
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SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	141
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9609-42	24 in 1 BOTTLE; Type 0: Not a Combination Product	06/05/2019	
2	NDC:0363-9609-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/03/2019	
3	NDC:0363-9609-09	1 in 1 CARTON	06/26/2021	
3		90 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	ANDA090545	06/03/2019	

Labeler - WALGREENS (008965063)

Registrant - TIME CAP LABORATORIES, INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LTD		925822975	manufacture(0363-9609)