

**BACK AND MUSCLE PAIN- naproxen tablet, coated
WALGREENS**

**609R WALGREENS BACK AND MUSCLE ALL DAY PAIN RELIEF NDC 0363-9609-42 &
(01)- NAPROXEN**

ACTIVE INGREDIENT

Naproxen Sodium Tablets, USP
220 mg (NSAID)*
*nonsteroidal anti-inflammatory drug

INACTIVE INGREDIENTS

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

PURPOSE

Pain reliever/ fever reducer

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

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

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

Allergy alerts: 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 blood thinning (anticoagulant) or steroid drug
- take other drug 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.

24 CT

Print & Varnish

60998 REV 0219

0-00000-00000-00000
NAPROXEN SODIUM TABLETS USP, 220 mg
MAY 2019
LOT: 180525221
0-00000-00000-00000
100% SATISFACTION GUARANTEED
© 2019 WALGREENS, A Division of
Walgreens Retail Stores, L.P.

READ AND KEEP LABEL FOR COMPLETE DIRECTIONS AND INFORMATION

Drug Facts (continued)	Drug Facts (continued)	Drug Facts (continued)
Drug Facts (continued) Use only if you have had no allergic reaction to any other pain reliever/fever reducer. Do not use if you are allergic to naproxen sodium, aspirin, or any other NSAID. Do not use if you are taking aspirin, ibuprofen, naproxen, or any other NSAID. Do not use if you are taking aspirin, ibuprofen, naproxen, or any other NSAID. Do not use if you are taking aspirin, ibuprofen, naproxen, or any other NSAID.	Drug Facts (continued) Do not use if you are taking aspirin, ibuprofen, naproxen, or any other NSAID. Do not use if you are taking aspirin, ibuprofen, naproxen, or any other NSAID. Do not use if you are taking aspirin, ibuprofen, naproxen, or any other NSAID. Do not use if you are taking aspirin, ibuprofen, naproxen, or any other NSAID.	Drug Facts (continued) Do not use if you are taking aspirin, ibuprofen, naproxen, or any other NSAID. Do not use if you are taking aspirin, ibuprofen, naproxen, or any other NSAID. Do not use if you are taking aspirin, ibuprofen, naproxen, or any other NSAID. Do not use if you are taking aspirin, ibuprofen, naproxen, or any other NSAID.

Walgreens

BACK & MUSCLE PAIN

All Day Pain Relief

NAPROXEN SODIUM TABLETS USP, 220 mg /

NEW

Compare to Aleve[®] Back and Muscle Pain active ingredient!



100 CT

Print & Varnish
Omit

Lot No: _____ Date: _____ Exp: _____

READ AND KEEP WITHIN REACH OF CHILDREN. WARNING: MAY BE HARMFUL IF SWALLOWED.

Drug Facts (continued)

Onset of action: You may feel an effect within 30 minutes.

Duration of action: The effect of Varnish Omit may last for up to 12 hours.

How to use: Take 1 tablet every 12 hours with food or a meal. Do not take more than 2 tablets in 24 hours. Do not take more than 10 days unless your doctor tells you to. If you are taking Varnish Omit for more than 10 days, you should see your doctor to see if you still need to take it. Do not take Varnish Omit if you are pregnant or trying to get pregnant. Tell your doctor if you are pregnant, trying to get pregnant, or if you are breastfeeding.

Warnings: Varnish Omit may cause a serious allergic reaction that may be life-threatening or even fatal. Tell your doctor if you have ever had an allergic reaction to any other pain reliever/fever reducer, aspirin, or other NSAID. Tell your doctor if you have ever had asthma, hives, or other allergic conditions. Tell your doctor if you have ever had stomach pain, ulcers, or bleeding in your stomach or intestines. Tell your doctor if you have ever had kidney disease, liver disease, or heart disease. Tell your doctor if you are taking any other medicines, especially blood thinners, because there may be a risk of bleeding. Tell your doctor if you are taking any other medicines, especially blood thinners, because there may be a risk of bleeding. Tell your doctor if you are taking any other medicines, especially blood thinners, because there may be a risk of bleeding.

Side effects: The most common side effects of Varnish Omit are: stomach pain, heartburn, indigestion, nausea, vomiting, constipation, diarrhea, dizziness, headache, and drowsiness. Tell your doctor if you experience any of these side effects. Tell your doctor if you experience any of the following signs of stomach bleeding: black or bloody stools, vomit that looks like coffee grounds, or vomit that looks like bright red blood. Tell your doctor if you experience any of the following signs of stomach bleeding: black or bloody stools, vomit that looks like coffee grounds, or vomit that looks like bright red blood.

Other information: Varnish Omit may contain some inactive ingredients. Tell your doctor if you have any allergies to these ingredients. Tell your doctor if you are taking any other medicines, especially blood thinners, because there may be a risk of bleeding. Tell your doctor if you are taking any other medicines, especially blood thinners, because there may be a risk of bleeding.

Drug Facts (continued)

Onset of action: You may feel an effect within 30 minutes.

Duration of action: The effect of Varnish Omit may last for up to 12 hours.

How to use: Take 1 tablet every 12 hours with food or a meal. Do not take more than 2 tablets in 24 hours. Do not take more than 10 days unless your doctor tells you to. If you are taking Varnish Omit for more than 10 days, you should see your doctor to see if you still need to take it. Do not take Varnish Omit if you are pregnant or trying to get pregnant. Tell your doctor if you are pregnant, trying to get pregnant, or if you are breastfeeding.

Warnings: Varnish Omit may cause a serious allergic reaction that may be life-threatening or even fatal. Tell your doctor if you have ever had an allergic reaction to any other pain reliever/fever reducer, aspirin, or other NSAID. Tell your doctor if you have ever had asthma, hives, or other allergic conditions. Tell your doctor if you have ever had stomach pain, ulcers, or bleeding in your stomach or intestines. Tell your doctor if you have ever had kidney disease, liver disease, or heart disease. Tell your doctor if you are taking any other medicines, especially blood thinners, because there may be a risk of bleeding. Tell your doctor if you are taking any other medicines, especially blood thinners, because there may be a risk of bleeding.

Side effects: The most common side effects of Varnish Omit are: stomach pain, heartburn, indigestion, nausea, vomiting, constipation, diarrhea, dizziness, headache, and drowsiness. Tell your doctor if you experience any of these side effects. Tell your doctor if you experience any of the following signs of stomach bleeding: black or bloody stools, vomit that looks like coffee grounds, or vomit that looks like bright red blood. Tell your doctor if you experience any of the following signs of stomach bleeding: black or bloody stools, vomit that looks like coffee grounds, or vomit that looks like bright red blood.

Other information: Varnish Omit may contain some inactive ingredients. Tell your doctor if you have any allergies to these ingredients. Tell your doctor if you are taking any other medicines, especially blood thinners, because there may be a risk of bleeding. Tell your doctor if you are taking any other medicines, especially blood thinners, because there may be a risk of bleeding.

AUTO-REORDER & SAVE

When you buy 100 tablets, you get 10% off the next purchase.

1. Add the Auto-Order & Save icon to your shopping cart.

2. Check out and you'll receive 10% off your next purchase.

3. The 10% discount will be applied to your next purchase.

4. The 10% discount will be applied to your next purchase.

5. The 10% discount will be applied to your next purchase.

6. The 10% discount will be applied to your next purchase.

7. The 10% discount will be applied to your next purchase.

8. The 10% discount will be applied to your next purchase.

9. The 10% discount will be applied to your next purchase.

10. The 10% discount will be applied to your next purchase.



AUTO-REORDER & SAVE

When you buy 100 tablets, you get 10% off the next purchase.

1. Add the Auto-Order & Save icon to your shopping cart.

2. Check out and you'll receive 10% off your next purchase.

3. The 10% discount will be applied to your next purchase.

4. The 10% discount will be applied to your next purchase.

5. The 10% discount will be applied to your next purchase.

6. The 10% discount will be applied to your next purchase.

7. The 10% discount will be applied to your next purchase.

8. The 10% discount will be applied to your next purchase.

9. The 10% discount will be applied to your next purchase.

10. The 10% discount will be applied to your next purchase.

TAKE 1 TABLET EVERY 12 HOURS WITH FOOD OR A MEAL. DO NOT TAKE MORE THAN 2 TABLETS IN 24 HOURS. DO NOT TAKE MORE THAN 10 DAYS UNLESS YOUR DOCTOR TELLS YOU TO. IF YOU ARE TAKING VARNISH OMIT FOR MORE THAN 10 DAYS, YOU SHOULD SEE YOUR DOCTOR TO SEE IF YOU STILL NEED TO TAKE IT. DO NOT TAKE VARNISH OMIT IF YOU ARE PREGNANT OR TRYING TO GET PREGNANT. TELL YOUR DOCTOR IF YOU ARE PREGNANT, TRYING TO GET PREGNANT, OR IF YOU ARE BREASTFEEDING.



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:5Y76R9ATQ)	NAPROXEN SODIUM	220 mg

Inactive Ingredients

Ingredient Name	Strength
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	

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)