# IBUPROFEN- ibuprofen capsule, liquid filled Kroger Company

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# **Kroger Ibuprofen Capsules 200mg**

# **DRUG FACTS**

# Active ingredient(in each capsule)

Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)' (present as the free acid and potassium salt)

\*nonsteroidal anti-inflammatory drug

# Purpose

Pain reliever/Fever reducer

# Uses

• temporarily relieves minor aches and pains due to:

headache

toothache

backache

menstrual cramps the common cold

muscular aches

minor pain of arthritis

• temporarily reduces fever

# Warnings

**Allergy alert:** Ibuprofen 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 waming:** 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.

# Do not use

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

# Ask a doctor before use if

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- 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

# 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 ibuprofen 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
- 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 ibuprofen 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.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

# **Directions**

- do not take more than directed
- the smallest effective dose should be used
- adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 capsule, 2 capsules may be used
- do not exceed 6 capsules in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

# OTHER INFORMATION

# Other information

- each capsule contains: potassium 20 mg
- read all warnings and directions before use
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F).

# Questions or comments? 1-800-632-6900

# Inactive ingredients

ammonium hydroxide, FD&C green #3, gelatin, iron oxide black, medium chain triglycerides, polyethylene glycol, potassium hydroxide, propylene glycol, purified water, shellac, sorbitan monooleate, sorbitol sorbitan



Varnish Omit Area

For More Product Information, Scan UPC Using Your Knoger App or Call 800-632-6900 OUR PHARMACIST O RECOMMENDED MADE IN INDIA

L0T:

EXP.

stroke you are taking a diuretic

erol trademark of Haleon US Holdings LLC, Haleon US Holdings LLC is not affiliated with The Kroger Co. Jiqui-dels is a registered trademark of Catalent Pharma Solutions, Inc. Catalent Pharma Solutions, Inc.

DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202

or this product. Liqui-Gels is a registered tradem is not affiliated with The Kroger Co. or this produ

*Drug Facts* (continued under label)

directed or for longer than directed

When using this product
■ take with food or milk if stomach upset occurs

chance is ligher if you: a see age 60 or older. In have had stomach ulers or beleding problems. It ake a blood thinning (anticoagulart) or steroid drug. It ake other drugs containing prescription or nonprescription NSAIDs (aspirin, blugnofen, naproxen, or others). In her 3 or more alcoholic drinks every day while using this product. It ake more or for a longer time than directed. It also the see the risk of heart attack of the second product increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than

■ you experience any of the following signs of stomach bleeding:
 ■ feel faint
 ■ vomit blood
 ■ have bloody or black

Allergy alert: Ibuprofen 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

If pregnant or breast-feeding, ask a health professional before use, it is especially important not to use buryorden 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

Directions

■ do not take more than directed
■ the smallest effective dose should be used
■ the smallest effective dose should be used
■ adults and children 12 years and over: take 1
capsule every 4 to 6 hours while symptoms persist
■ if pain or fever dose not respond to 1 capsule, 2

■ children under 12 years: ask a doctor

DO NOT USE IF SEAL FOR YOUR ACTUAL SIZE

**Drug Facts** 

■ each capsule contains: potassium 20 mg ■ read all warnings and directions before use ■ store at 20-25°C (68-77°F) ■ avoid excessive heat above 40°C (104°F) Other information

propylene glycol, purified water, shellac, sorbitan monooleate, sorbitol sorbitan

**Questions?** Call 1-800-632-6900

Adhesive Area

PAIN RELIEVER/ FEVER REDUCER (NSAID)\*

80 SOFTGELS

**Drug Facts** (continued)

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 stomach bleeding warning applies to you super blems or serious side effects from taking pain relievers or fever reducers 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

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 ibuproflen may decrease this benefit of aspirin taking any other drug

Stop use and ask a doctor if

stools have stomach pain that does not get better
you have symptoms of heart problems or stroke:
Chest pain at trouble breathing weakness in one
part or side of body submore than 10 days
pain gets worse or lasts more than 10 days
fever gets worse or lasts more than 3 days
fever gets worse or lasts more than 10 more than 10 days
fever gets worse or lasts more than 10 days
fever gets worse or lasts more than 10 days
fever gets worse or lasts more than 10 days
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fever gets worse or lasts more than 3 days
fever gets worse or lasts worse or last more than 10 days
fever gets worse or lasts more than 3 days
fever gets worse or lasts more than 10 days

any new symptoms appear

get medical help or contact a Poison Control Center right away (1-800-222-1222). Keep out of reach of children. In case of overdose,

capsules may be used

Purpose

Pain reliever/

present as the free acid and potassium salt) Fever reducer

200 mg ibuprofen (NSA

solubilized ibuprofen Active ingredient (in each capsule)

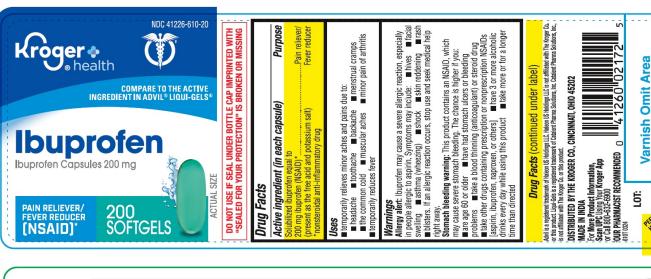
equal to

■ temporarily relieves minor aches and pains due to:
■ headache ■ toothache ■ backache

■ menstrual cramps ■ the common cold ■ muscular aches ■ minor pain of arthritis ■ temporarily reduces fever

■ do not exceed 6 capsules in 24 hours, unless directed

Inactive Ingredients ammonium hydroxide, FD&C green #3, gelatin, iron oxide black, medium chain iglycerides, polyethylene glycol, potassium hydroxide



# Drug Facts (continued)

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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 attack.

pain reliever/fever reducer Do not use if you have ever had an allergic reaction to any other

■ right before or after heart surgery

Ask a doctor before use if stomach bleeding warning applies to you syou have problems or serious side effects from taking pain relievers or fever reducers you have a history of stomach Ask a doctor or pharmacist before use if you are heart disease, liver cirrhosis, kidney disease, asthma, or had a problems, such as heartburn you are taking a diuretic you have high blood pressure

■ taking aspirin for heart attack or stroke, because ibuprofen may ■ under a doctor's care for any serious condition

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 ■ 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 ibuprofen 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

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions ■ do not take more than directed ■ the smallest effective dose should be used

hours while symptoms persist ■ adults and children 12 years and over: take 1 capsule every 4 to 6

■ if pain or fever does not respond to 1 capsule, 2 capsules may be doctor ■children under 12 years: ask a doctor used ■ do not exceed 6 capsules in 24 hours, unless directed by a

# Other information each capsule contains: potassium 20 mg eread all warnings and directions before use store at 20-25°C (68-77°F) avoid excessive heat above 40°C.

glycol, potassium hydroxide, propylene glycol, purified water shellac, sorbitan monooleate, sorbitol sorbitan gelatin, iron oxide black, medium chain triglycerides, polyethylene Inactive ingredients ammonium hydroxide, FD&C green #3

Questions or comments? Call 1-800-632-6900

Adhesive Area



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

Pain reliever/Fever reducer 

Altergy alert. Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

inves a facial swelling a sathma (wheezing)

shock a skin reddening a sash a blisters.

Directions ■ do not take more than directed ■ the smallest effective dose should be used ■ adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist ■ if pain or fever dose not respond to 1 capsule. 2 capsules may be used ■ do not exceed 6 capsules in the dot of the capsules have the dot of the capsules of the

Other information = each capsule contains: polassium 20 mg = read all warnings and directions before use = store at 20-29° (68-77°) = avoid excessive heat above 40°C (104°F).

rears: ask a doctor

Inactive ingredients ammonium hydroxide, FD&C green 23. gelatin, iron oxide black, medium chain trigiveendes, polyetriylene glycol, potassium hydroxide, propylene glycol, purified water, shalkac, sorbitan monobata, sorbital sorbital

Questions or comments? Call 1-800-632-6900

are age 60 or older

have flad stomach ulers or bleeding problems

take a blood thinning (articoaglart) or steroid drug

take a blood thinning prescription or nonprescription NSAIDs

(aspirin, ibuprofen, naproxen, or others)

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

Take more or for a longer time than directed

# *Drug Facts* (continued under label)

1 Advil is a registered trademark of GlaxoSmithkline Consumer Healthcare Holdings (US) LLC, Minnington, DE 19808. GlaxoSmithkline Consumer Healthcare Holdings (US) LLC, shord frillitoted with The Knager Co. or this product. Liqui-Gels is a registered trademark of Catalent Pharma Solutions. Inc., Someset, NI 08873. Catalent Pharma Solutions. Inc., is not afflicited with The Krager Co. or this product.

PHERE

surgery

Ast a dotto before use if stomach bleeding warning

Ast a dotto before use if stomach bleeding warning

applies to you I you have problems or serious side effects
from taking pain relievers or fewer reducers I you have a
history of stomach problems, such as hearbrum II you have
high blood pressure, heart cisease, liver cirrhosis, kidney
disease, asthma, or had a stroke I you are taking a diuretic

Ast a doctor or harmackit before use if you are I mider a
doctor's care for any serious condition III sking aspirin for
heart attack or stroke, because ibuprojen may decrease this

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

Heart attack and stroke warning. NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. The can be fatal. The risk is higher if you use more than directed for Jonger than directed.

Drug Facts (continued)

benefit of aspirin staking any other drug

When using this product stake 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:

Active ingredient (in each capsule)

• feel faint • vornit blood • have bloody or black stools
• have stomech pain that does not get better

• under stomech pain that does not get better
• you have symptoms of heart problems or stoke.

• othest pain • trouble breathing • weakness in one part or side of body • subrind speed • leg swelling

• pain gets worse or lasts more than 10 days • if ever gets worse or lasts more than 10 days • if ever gets worse or lasts more than 10 days • if ever gets worse or lasts more than 3 days • if enthese or swelling is present in the painful area • any two symptomics appear

If pregnant or breast-leading, ask a health professional before use. It is especially important not to use bupurden 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.

Keep out of reach of children, in case of overdose, get medical help or condact a Poison Control Center right away (1-800-222-1222).

- temporarily relieves minor aches and pains due to:

   headache loodhathe Dackache menstrual cramps

   the common cold muscular aches minor pain of arthritis

   temporarily reduces flever

f 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:

DIST. BY THE KROGER CO., CINCINNATI, OHIO 45202

MADE IN IN INDIA

MADE IN INDIA

Lot No.:

Exp. Date:

Von Varnish Area



buprofen Capsules 200 mg

PAIN RELIEVER/ FEVER REDUCER (NSAID)\*

Adhesive Area

20 SOFTGELS

DO NOT USE IF SEAL UNDER BOTTLE CAP IMPRINTED WIT "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSIN WARNINGS AND PRODUCT INFORMATION temporarily relieves minor aches and pains

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

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic skin reddening, rash, blisters. If an allergic reaction occurs, stop use and seek medical facial swelling, asthma (wheezing), shock, to aspirin. Symptoms may include: hives, Warnings

help right away.

take 1 capsule every 4 to 6 hours adults and children 12 years and over:

while symptoms persist

be used

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if take a blood thinning (anticoagulant) or you ■are age 60 or older ■have had stomach ulcers or bleeding problems

Directions

do not take more than directed

the smallest effective dose should

of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222)

Keep out of reach of children. In case If pregnant or breast-feeding, ask a health professional before use.

have 3 or more alcoholic drinks every day while using this product at take more or [aspirin, ibuprofen, naproxen, or others] for a longer time than directed

leart attack and stroke warning: NSAIDs,

Drug Facts (continued under label)



Varnish Omit Area

OUR PHARMACIST RECOMMENDED For More Product Information, Scan UPC Using Your Kroger App or Call 800-632-6900 DISTRIBUTED BY THE KROGER CO. CINCINNATI, OHIO 45202 Questions or comments? Call 1-800-632-6900 each capsule contains: potassium MADE IN INDIA Other information 20 mg unless directed by a doctor children under 12 years: ask a doctor if pain or fever does not respond to 1 l do not exceed 6 capsules in 24 hours, capsule, 2 capsules may be used

except aspirin, increase the risk of heart attack, heart failure, and stroke. These Drug Facts (continued)

more than directed or for longer than can be fatal. The risk is higher if you use

directed.



# Varnish/Print Omit Area

Kroger • health



NDC 41226-610-23

COMPARE TO THE ACTIVE INGREDIENT IN ADVIL® LIQUI-GELS®

# lbuprofen

Ibuprofen Capsules 200 mg

PAIN RELIEVER/FEVER

20 SOFTGELS

ACTUAL SIZE

Varnish Omit

REDUCER (NSAID)

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

Allergy elert: buprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: 

In his set a facial swelling symptoms may include:

In his set a facial swelling asthmat wheeting)

In shock a skin meddening asthmat wheeting in the cocurs, stop use and seek medical help right away.

Stomach beeding warning: This product contains an NSAID which may cause severe stomach bleeding. The chance is higher if you are age 60 or older.

In wave had stomach ulces to bleeding problems at take a blood thinning (anticoagulant) or steroid drug at take other drugs containing prescription or nonprescription NSAIDs (sapplin, buprofen, naproven, or others).

In have 3 or more

coholic drinks every day while using this product

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 ▶

Other information ■ each capsule contains: potassium 20 mg ■ read all warnings and directions before use ■ store at 20-25°C (68-77°F) ■ avoid

excessive heat above 40°C

(F)

When using this product take with food or milk if stomach

upset occurs

# 200 mg ibuprofen (NSAI (present as the free acid an Active ingredient (in each capsule) Purpose

free acid and potassium salt) Fever reduce Pain reliever

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 stomach bleeding warning applies to you you have problems or serious side effects from taking pain relievers or fever reducers at you have a instory 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

Ask a doctor or pharmacist before use if you are under a doctor's care for any serious condition taking aspirin for hearl attack or stroke, because ibuprotein may decrease this benefit of aspirin taking any other drug If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or latter in 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 right away (1-800-222-1222).

Directions ■ do not take more than directed
■ the smallest effective dose should be used
■ adults and children 12 years and over: take 1
capsule every 4 to 6 hours while symptoms persist
■ if pain or fever doses not respond to 1 capsule, 2
capsules may be used ■ do not exceed 6 capsules
in 24 hours, unless directed by a doctor
■ children under 12 years; ask a doctor

Drug Facts (continued)

get better 
you have symptoms of heart problems or stroke: 
• chest pain • trouble breathing 
• weakness in one part or side or body • surred 
speech • leg swelling 
pain gets worse or lasts more than 10 days 
fever gets worse or lasts more 
than 3 days 
frobless or swelling is present in the 
painful area 
any new symptoms appear

■ 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. Drug Facts (continued)

Drug Facts

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And it a registred brakman of leader 10 toolings LC. Haven IC Havings And to a registred with 16 Keyper No. or the product Lead-666 is a registred bushwan of Colleges Marine Solutions, Inc. Calabert Hawas Solutions, Inc. is and affiliated with This Mogel No. or this product.

DO NOT USE IF SEAL UNDER BOTTLE CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING

5

Varnish Omit

shellac, sorbitan monooleate 1-800-632-6900

Varnish Omit

Drug Facts (continued)

Inactive ingredients ammonium hydroxide, FD&C green #3, gelatin, iron oxide black, medium chain triglycerides, polyethylene glycol, potassium hydroxide, propylene glycol, purified water,

# **IBUPROFEN**

ibuprofen capsule, liquid filled

# **Product Information**

	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41226-610
ı	Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg		

Inactive Ingredients			
Ingredient Name	Strength		
GELATIN (UNII: 2G86QN327L)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)			
WATER (UNII: 059QF0KO0R)			
SHELLAC (UNII: 46N107B710)			
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)			
AMMONIA (UNII: 5138Q19F1X)			
FERROUS OXIDE (UNII: G7036X8B5H)			
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SORBITOL (UNII: 506T60A25R)			

Product Characteristics				
Color	green	Score	no score	
Shape	CAPSULE	Size	19mm	
Flavor		Imprint Code	133	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:41226-610- 66	160 in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2021			
2	NDC:41226-610- 20	200 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2024			
3	NDC:41226-610- 23	1 in 1 CARTON	04/15/2024			
3		20 in 1 BOTTLE; Type 0: Not a Combination Product				
4	NDC:41226-610- 80	80 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2024			

Marketing Information					
Marketing	Application Number or Monograph	Marketing Start	Marketing End		
Category	Citation	Date	Date		

ANDA	ANDA079205	06/12/2021	

# Labeler - Kroger Company (006999528)

# **Registrant -** TIME CAP LABORATORIES, INC. (037052099)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
MARKSANS PHARMA LIMITED		925822975	manufacture(41226-610)	

Revised: 4/2024 Kroger Company