

IBUPROFEN- ibuprofen tablet, coated
RITE AID CORPORATION

600R RITE AID 11822 7891 IBUPROFEN 200 MG CAPLETS

DRUG FACTS

Active ingredient (in each caplet)

Ibuprofen 200 mg (NSAID)*

* nonsteroidal anti-inflammatory drug

Purpose

Pain reliever / Fever reducer

Uses temporarily relieves minor aches and pains due to :

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

temporarily reduces fever

Warnings

Allergy alert: Ibuprofen 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 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: NSAID's, 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 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

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

Ask a doctor or pharmacist before use if you are

- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- 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

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 problem 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 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 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 older:**

take 1 caplet every 4 to 6 hours while symptoms persist

if pain or fever does not respond to 1 caplet, 2 caplets may be used

do not exceed 6 caplets in 24 hours, unless directed by a doctor.

- **children under 12 years:** ask a doctor

Other information

- read all warnings and directions before use
- store at 20-25°C (68-77°F)

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide

Questions or comments? Call 1-877-290-4008

NDC 11822-7891-5

**PAIN RELIEF
IBUPROFEN**

IBUPROFEN CAPLETS USP, 200 mg

**PAIN RELIEVER
FEVER REDUCER
(NSAID)**

100
CAPLETS**
(**CAPSULE-SHAPED
TABLETS)

Read all product information before using. Keep the box for important information.

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

■ temporarily reduces fever

Warnings **Allergy alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: ■ asthma (wheezing) ■ 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 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. It is especially important not to use ibuprofen 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 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 caplet every 4 to 6 hours while symptoms persist ■ if pain or fever does not respond to 1 caplet, 2 caplets may be used ■ do not exceed 6 caplets in 24 hours, unless directed by a doctor ■ **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.** ■ read all warnings and directions before use ■ store at 20-25°C (68-77°F)

Questions or comments? Call 1-877-290-4008

DISTRIBUTED BY: RITE AID. **SATISFACTION GUARANTEE:**
30 HUNTER LANE, CAMP HILL, PA 17011 If you're not satisfied, we'll happily
www.riteaid.com **MADE IN INDIA** refund your money. 600R 0821

Lot No.:
Exp. Date:

Coating/Print Omit Area



Lot No.: Exp. Date:
www.trifid.com MADE IN INDIA
DISTRIBUTED BY: TRIFID
SANSKRITION GUARANTEED
If you're not satisfied, we'll happily refund your money.

Read all product information before using. Keep the box for important information.

Drug Facts

Active ingredient (in each caplet) Purpose
Ibuprofen
200 mg (NSAID)*.....Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Uses

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

Warnings

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

Drug Facts (continued)

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 ibuprofen or any other pain reliever/fever reducer
right before or after heart surgery

Ask a doctor before use if

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

Ask a doctor or pharmacist before use if you are

- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
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

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 problem or stroke: chest pain, trouble breathing

Drug Facts (continued)

- weakness in one part or side of the 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 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 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 caplet every 4 to 6 hours while symptoms persist; if pain or fever does not respond to 1 caplet, 2 caplets may be used; do not exceed 6 caplets in 24 hours, unless directed by a doctor
children under 12 years: ask a doctor

Other information

- read all warnings and directions before use
store at 20-25°C (68-77°F)



Compare to the active ingredient in Advil® Caplets*

PAIN RELIEF
IBUPROFEN

IBUPROFEN CAPLETS USP, 200 mg
PAIN RELIEVER/FEVER REDUCER (NSAID)

ACTUAL SIZE
100 CAPLETS**

(**CAPSULE-SHAPED TABLETS)



NDC 11822-7891-5

E827R1

Coating/Print Omit Area



Drug Facts (continued)
Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, etc., titanium dioxide
Questions or comments? Call 1-877-290-4008
*Compare to the active ingredient in Advil® Caplets. **Actual size.
DANGER: EXPLOSION - DO NOT USE THIS PRODUCT IF THE UNPRINTED SEAL OVER THE MOUTH OF THE BOTTLE IS NOT TIGHT, BROKEN OR MISSING

NDC 11822-7891-9

Compare to the active ingredient in **Advil® Caplets**!

PAIN RELIEF
IBUPROFEN
IBUPROFEN CAPLETS USP, 200 mg
PAIN RELIEVER/FEVER REDUCER (NSAID)
ACTUAL SIZE
500 CAPLETS** (**CAPSULE-SHAPED TABLETS)

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

NDC 11822-7891-2

PAIN RELIEF
IBUPROFEN
IBUPROFEN CAPLETS USP, 200 mg
PAIN RELIEVER
FEVER REDUCER (NSAID)
50 CAPLETS** (**CAPSULE-SHAPED TABLETS)

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

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

Warnings Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: ■ asthma (wheezing) ■ hives ■ facial swelling ■ hives ■ rash ■ shock ■ skin redness ■ 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 genital area ■ any new symptoms appear

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 caplet every 4 to 6 hours while symptoms persist ■ if pain or fever does not respond to 1 caplet, 2 caplets may be used ■ do not exceed 6 caplets in 24 hours, unless directed by a doctor

children under 12 years: ■ ask a doctor

Other information ■ read all warnings and directions before use ■ store at 20-25°C (68-77°F)

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide

Questions or comments? Call 1-877-290-4008

Drug Facts

Active ingredient (in each tablet)
Ibuprofen 200 mg (NSAID)*
*nonsteroidal anti-inflammatory drug

Purpose
Pain reliever/fever reducer

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

Warnings
Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
■ asthma (wheezing) ■ hives ■ facial swelling ■ hives ■ rash ■ shock ■ skin redness ■ trouble breathing ■ weakness in one part or side of body ■ slurred speech ■ leg swelling

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Questions or comments? Call 1-877-290-4008

Drug Facts (continued under label)

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
■ you have stomach pain that does not get better
■ you have symptoms of heart problem 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 genital area ■ any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen 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 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 caplet every 4 to 6 hours while symptoms persist ■ if pain or fever does not respond to 1 caplet, 2 caplets may be used ■ do not exceed 6 caplets in 24 hours, unless directed by a doctor

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Questions or comments? Call 1-877-290-4008

Drug Facts (continued under label)

This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Advil® Caplets. 600R 0821

DISTRIBUTED BY: RTE AD
30 HUNTER LANE
CHAMP HILL, PA 17011
www.rtead.com MADE IN INDIA

SATISFACTION GUARANTEE:
If you're not satisfied, we'll happily refund your money.
*HILL470 Code No.: G0DRUGS515

Lot No.: 1182278920 2
Exp. Date:

PREP HERE

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

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

Warnings Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: ■ asthma (wheezing) ■ hives ■ facial swelling ■ hives ■ rash ■ shock ■ skin redness ■ 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 genital area ■ any new symptoms appear

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adults and children 12 years and over: ■ take 1 caplet every 4 to 6 hours while symptoms persist ■ if pain or fever does not respond to 1 caplet, 2 caplets may be used ■ do not exceed 6 caplets in 24 hours, unless directed by a doctor

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Other information ■ read all warnings and directions before use ■ store at 20-25°C (68-77°F)

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Questions or comments? Call 1-877-290-4008

Drug Facts (continued under label)

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
■ you have stomach pain that does not get better
■ you have symptoms of heart problem 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 genital area ■ any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen 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 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 caplet every 4 to 6 hours while symptoms persist ■ if pain or fever does not respond to 1 caplet, 2 caplets may be used ■ do not exceed 6 caplets in 24 hours, unless directed by a doctor

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Other information ■ read all warnings and directions before use ■ store at 20-25°C (68-77°F)

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Questions or comments? Call 1-877-290-4008

Drug Facts (continued under label)

This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Advil® Caplets. 600R 0821

DISTRIBUTED BY: RTE AD
30 HUNTER LANE
CHAMP HILL, PA 17011
www.rtead.com MADE IN INDIA

SATISFACTION GUARANTEE:
If you're not satisfied, we'll happily refund your money.
*HILL469 Code No.: G0DRUGS515

Lot No.: 1182278920 2
Exp. Date:

PREP HERE



IBUPROFEN

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-7891
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	200 mg

Inactive Ingredients

Coating/Print Omit Area



Lot No.: 11822789172
 Exp Date: 2
 This product is not manufactured or distributed by
 Pfizer Consumer Healthcare, owner of the registered
 trademark Advil® Caplets, 6000 0021
 DISTRIBUTION QUAINTANCE
 30 HARTLEY COURT, PO BOX 17011
 TAMPA, FL 33613
 www.pfizer.com
 supply reduced your money.

Code: GDUK5/S15

Important: Read all product information before using.
 Keep this box for important information.

Drug Facts

Active ingredient (in each caplet) Purpose

ibuprofen
 200 mg (NSAID)* Pain reliever/Fever reducer
 *nonsteroidal anti-inflammatory drug

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

Warnings

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

Symptoms may include: ■ asthma (wheezing)
 ■ hives ■ facial swelling ■ rash
 ■ shock ■ skin reddening. If an allergic reaction occurs, stop use and seek medical help right away.

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 ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed

Drug Facts (continued)

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 after heart surgery

Ask a doctor before use if ■ you have problems or serious side effects from taking pain relievers or fever reducers ■ 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

Ask a doctor or pharmacist before use if you are

■ taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
 ■ 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

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

Drug Facts (continued)

■ you have symptoms of heart problem 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 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 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 older:

■ take 1 caplet every 4 to 6 hours while symptoms persist
 ■ if pain or fever does not respond to 1 caplet, 2 caplets may be used ■ do not exceed 6 caplets in 24 hours, unless directed by a doctor

children under 12 years:

■ ask a doctor

Other information

■ read all warnings and



Coating Omit

Compare to the active ingredient in Advil® Caplets*

PAIN RELIEF
IBUPROFEN
 IBUPROFEN CAPLETS USP, 200 mg
 PAIN RELIEVER/FEVER REDUCER
 (NSAID)

ACTUAL SIZE
50
 CAPLETS*
 (1 CAPSULE-SHAPED TABLET)



NDC:11822-7891-2

Coating Omit



E826R1 Coating/Print Omit Area

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	brown	Score	no score
Shape	CAPSULE ((CAPLET))	Size	15mm
Flavor		Imprint Code	117
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-7891-5	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
2	NDC:11822-7891-2	50 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
3	NDC:11822-7891-9	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091239	06/01/2020	

Labeler - RITE AID CORPORATION (014578892)

Registrant - TIME CAP LABORATORIES, INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LTD		925822975	manufacture(11822-7891)