ACETAMINOPHEN- acetaminophen tablet
RAONBIO CORP

Acetaminophen and Ibuprofen (NSAID) tablets 250mg/125mg
Dual Action
Pain Reliver

Active ingredients (in each caplet)

Acetaminophen 250 mg

Ibuprofen 125 mg (NSAID**)

Purposes

Pain Reliever

Uses

■ temporarily relieves minor aches and pains due to:
■ headache ■ toothache ■ backache ■ menstrual cramps ■ muscular aches ■ minor pain of arthritis

Warnings

Acetaminophen liver damage warning:

This product contains acetaminophen. Severe liver damage may occur if you take:
■ with other drugs containing acetaminophen

■ more than 6 caplets in 24 hours, which is the maximum daily amount for this product
■ 3 or more alcoholic drinks every day while using this product

Acetaminophen allergy alert: may cause severe skin reactions.
Symptoms may include:
■ skin reddening ■ blisters ■ rash
If skin reaction occurs, stop use and seek medical help right away.

NSAID 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.

Warnings

NSAID 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.

Do not use

■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

■ if you have ever had an allergic reaction to acetaminophen or any other pain reliever
■ right before or after heart surgery

Ask a doctor before use if

■ you have liver disease ■ stomach bleeding warning applies to you
■ you have problems or serious side effects from taking pain relievers
■ 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
■ 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. Prompt medical attention is critical for adults
as well as for children even if you do not notice any signs or symptoms.

Directions

■ do not take more than directed

adults and children 12 years and over ■ take 2 caplets every 8 hours while symptoms persist

children under 12 years ■ ask a doctor

■ do not take more than 6 caplets in 24 hours, unless directed by a doctor

Other information

■ read all warnings and directions before use. Keep carton.
■ store at 20 to 25°C (68 to 77°F)
■ avoid excessive heat above 40°C (104°F)

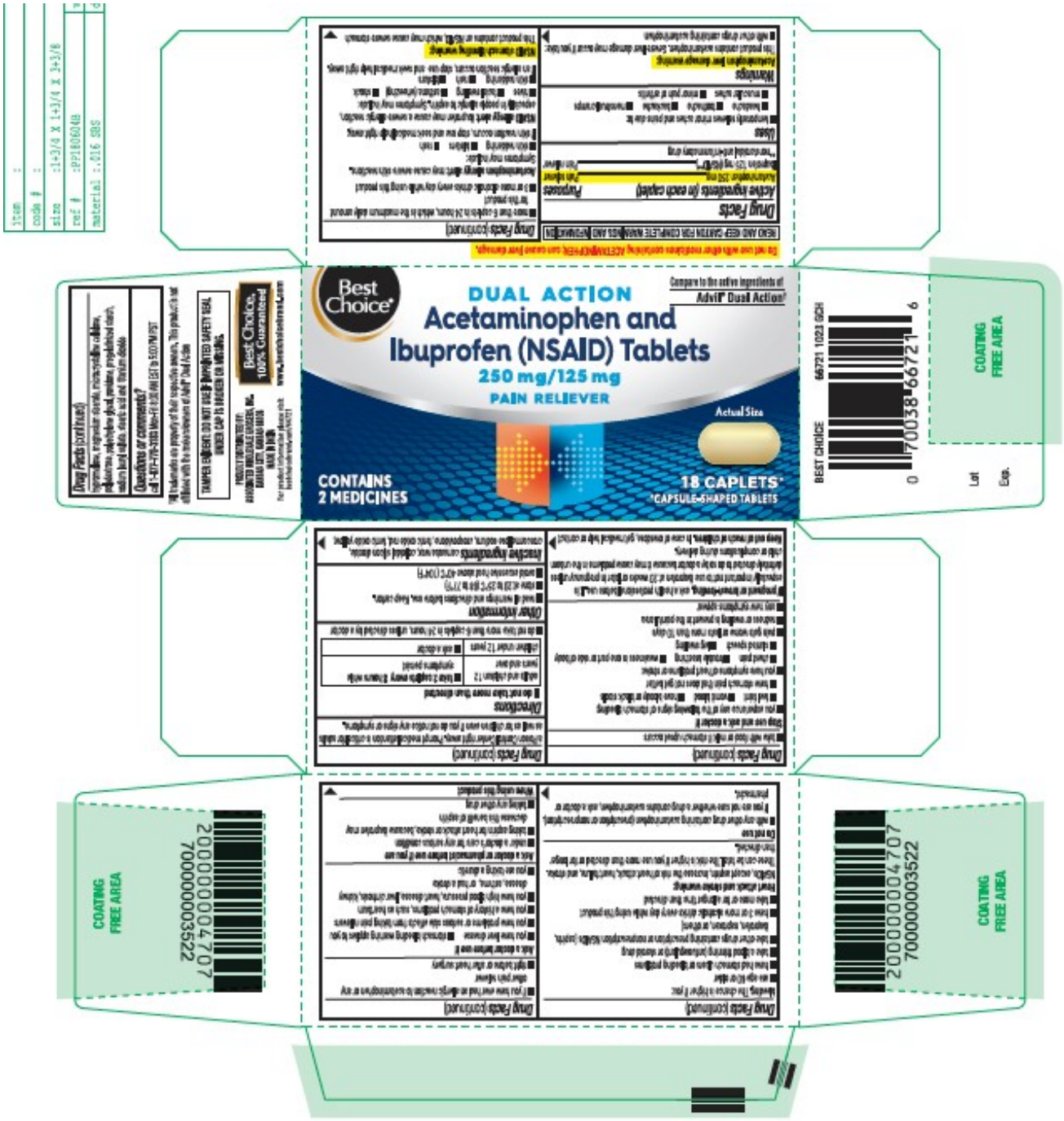
Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, crospovidone, ferric oxide red, ferric oxide yellow, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, pregelatinized starch, sodium lauryl sulfate, stearic acid and titanium dioxide

Questions or comments?

call **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST

PDP


DUAL ACTION
Acetaminophen and Ibuprofen (NSAID) Tablets
250 mg/125 mg
PAIN RELIEVER
Compare to the active ingredients of Advil® Dual Action®
Actual Size
CONTAINS 2 MEDICINES
18 CAPLETS*
*CAPSULE-SHAPED TABLETS
Best Choice®
Best Choice, 100% Guaranteed
COATING FREE AREA
BEST CHOICE
Drug Facts
Drug Facts (continued)
Drug Facts (continued)
Drug Facts (continued)

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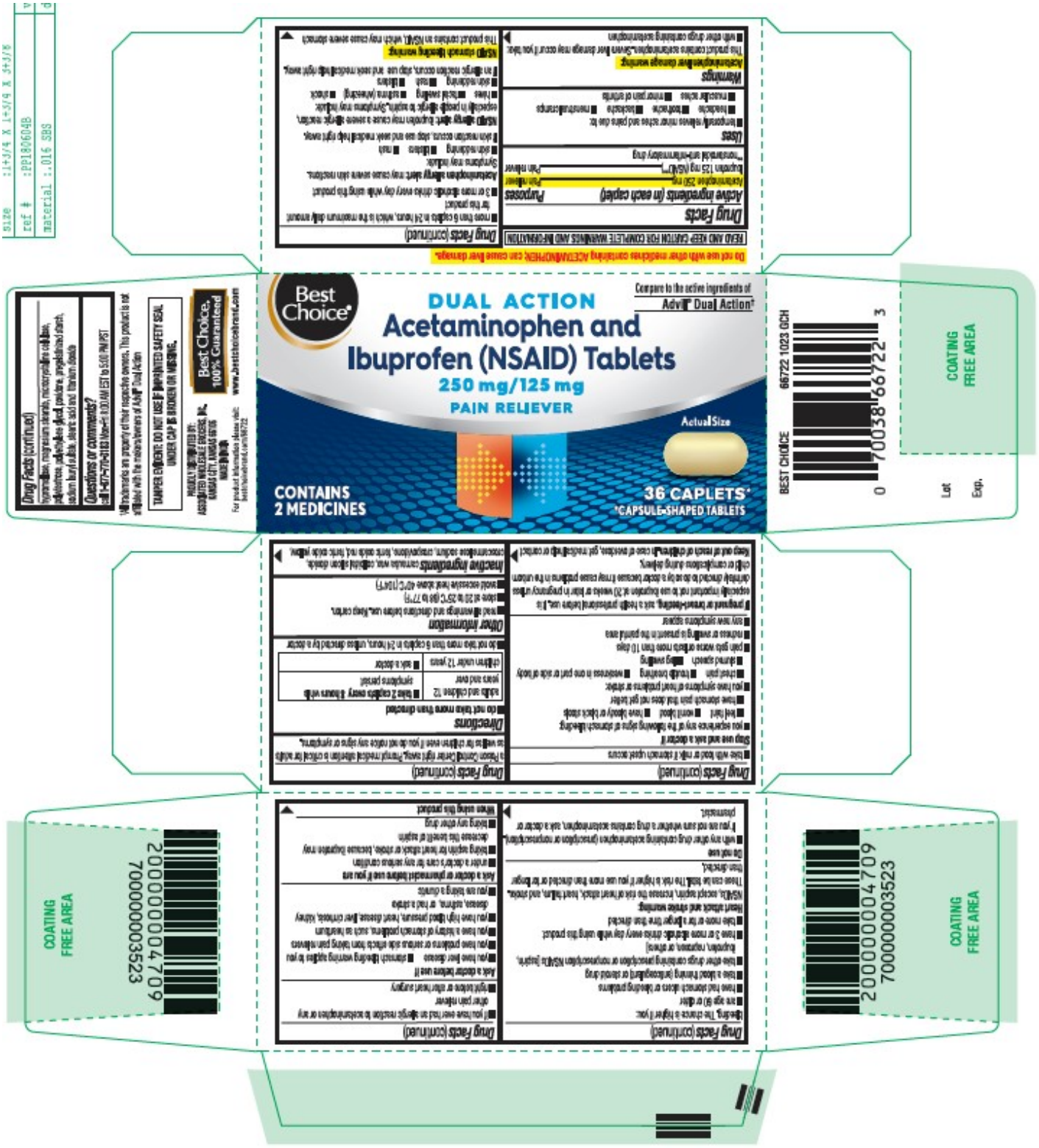
DUAL ACTION
Acetaminophen and Ibuprofen (NSAID) Tablets
250 mg/125 mg
PAIN RELIEVER
Compare to the active ingredients of Advil® Dual Action®
Best Choice
Actual Size
CONTAINS 2 MEDICINES
36 CAPLETS*
*CAPSULE-SHAPED TABLETS
Best Choice, 100% Guaranteed
www.bestchoicebrands.com
TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.
Drug Facts
Active ingredients (in each caplet)
Purposes
Acetaminophen 250 mg
Pain reliever
Ibuprofen 125 mg (NSAID*)
Pain reliever
*nonsteroidal anti-inflammatory drug
Uses
temporarily relieves minor aches and pains due to:
headache
toothache
backache
menstrual cramps
muscular aches
minor pain of arthritis
Warnings
Acetaminophen liver damage warning
This product contains acetaminophen. Severe liver damage may occur if you take:
more than 6 caplets in 24 hours, which is the maximum daily amount for this product
8 or more alcoholic drinks every day while using this product
Acetaminophen allergy alert: may cause severe skin reactions. Symptoms may include:
skin reddening
blisters
rash
If a skin reaction occurs, stop use and seek medical help right away.
NSAID 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
blisters
rash
If an allergic reaction occurs, stop use and seek medical help right away.
NSAID stomach bleeding warning
This product contains an NSAID, which may cause severe stomach bleeding
Do not use with other medicines containing ACETAMINOPHEN: can cause liver damage.
READ AND KEEP CAUTION FOR COMPLETE WARNINGS AND INFORMATION
Drug Facts (continued)
Do not use
with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
if you have ever had an allergic reaction to acetaminophen or any other pain reliever
if you have had an allergic reaction to any ingredient in this product
if you have had asthma, hives, or other allergic reaction after taking aspirin or any other NSAID (ibuprofen, naproxen, or others)
if you have 3 or more alcoholic drinks every day while using this product
if you have or have had heart disease, heart attack, angina, heart failure, or stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.
Ask a doctor before use if
you have ever had stomach bleeding or ulcers
you have bleeding problems
you have kidney disease. Your risk of kidney failure is greater if you already have kidney disease.
you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or fluid retention
you are taking a diuretic
you are taking corticosteroids, alcohol, or SSRIs (such as fluoxetine or sertraline)
you are taking an anticoagulant (such as warfarin) or an SSRI (such as fluoxetine or sertraline)
you are taking lithium
you are taking methotrexate
you are taking pemetrexed
you are 65 or older
you are pregnant in the third trimester
you are taking other drugs containing NSAIDs
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
Drug Facts (continued)
Reye's Cereal Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.
Directions
do not take more than directed
adults and children 12 years and over
take 2 caplets every 4 hours with symptoms persist
children under 12 years
ask a doctor
do not take more than 6 caplets in 24 hours, unless directed by a doctor
Other information
read all warnings and directions before use. Keep carton.
store at 20 to 25°C (68 to 77°F)
avoid excessive heat above 40°C (104°F)
Inactive ingredients
Carnauba wax, colloidal silicon dioxide, croscarmellose sodium, crospovidone, ferric oxide red, ferric oxide yellow, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, polysorbate 80, propylene glycol, pregelatinized starch, sodium lauryl sulfate, stearic acid and titanium dioxide
Questions or comments?
call 1-877-757-0183 Mon–Fri 8:00 AM EST to 5:00 PM PST
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For product information please visit: bestchoiceford.com/66722
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COATING FREE AREA
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material :.016 SBS

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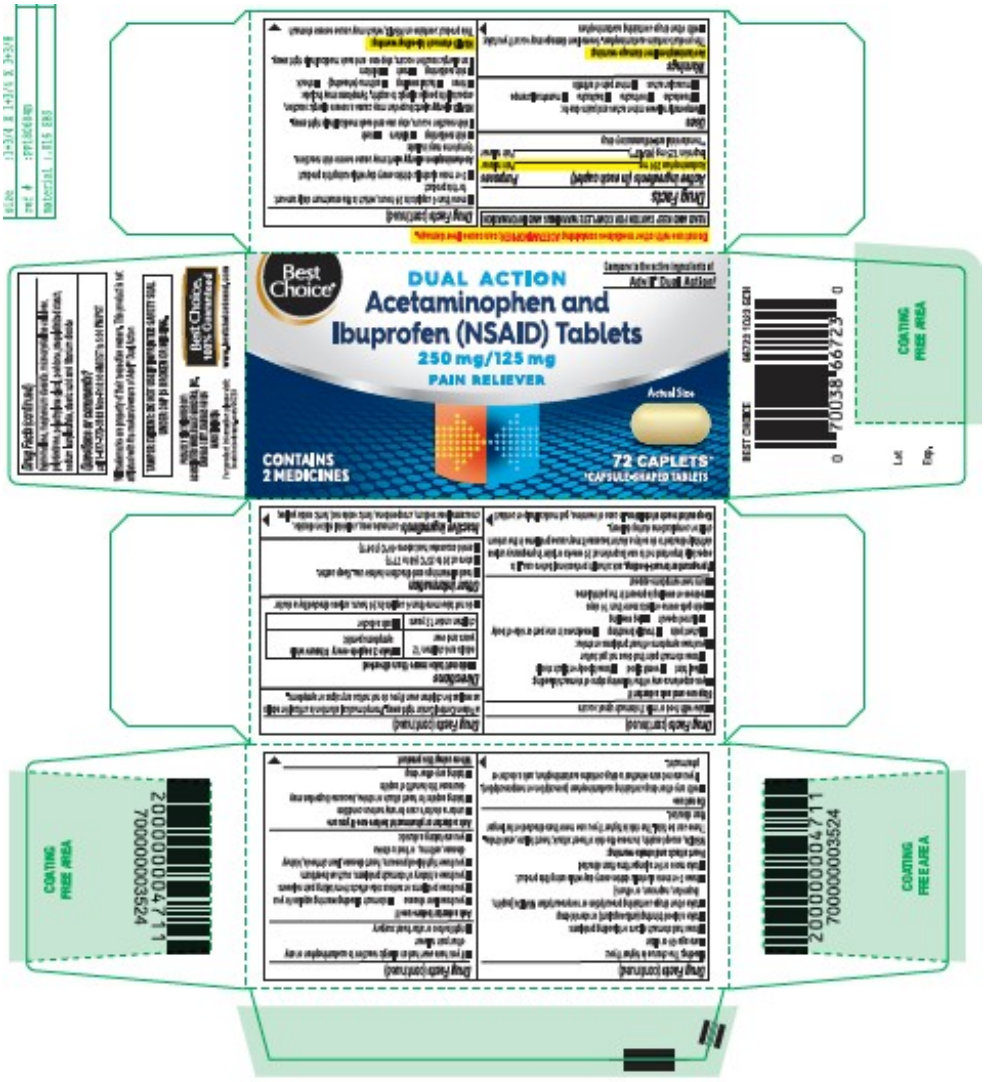

ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70038-131
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	125 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE K30 (UNII: U725QWY32X)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	yellow ((Light yellow to yellow colored))	**Score**	no score
Shape	CAPSULE ((capsule shaped, biconvex))	**Size**	14mm
Flavor		**Imprint Code**	G;131
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70038-131-81	18 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2024	
2	NDC:70038-131-36	36 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2024	
3	NDC:70038-131-72	72 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216592	01/01/2024	

Labeler - RAONBIO CORP (689517161)

Revised: 11/2023 RAONBIO CORP