ADVIL- ibuprofen tablet, coated
Haleon US Holdings LLC

Drug Facts

Active Ingredient

Advil Tablets (in each tablet)

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Advil Caplets (in each caplet)

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Advil Gel Caplets (in each gel caplet)

Ibuprofen 200 mg (NSAID)*

*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 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 non-prescription 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 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
- 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.

Directions

Advil Tablets

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

Advil Caplets

- **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

Advil Gel Caplets

- **do not take more than directed**
- **the smallest effective dose should be used**
- adults and children 12 years and over: take 1 gel caplet every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 gel caplet, 2 gel caplets may be used
- do not exceed 6 gel 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. Keep carton.
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

Advil Tablets

acetylated monoglycerides, colloidal silicon dioxide, corn starch, croscarmellose sodium, methylparaben, microcrystalline cellulose, pharmaceutical glaze, pharmaceutical ink, povidone, pregelatinized starch, propylparaben, sodium benzoate, sodium lauryl sulfate, stearic acid, sucrose, synthetic iron oxide, titanium dioxide, white wax

Advil Caplets

acetylated monoglycerides, colloidal silicon dioxide, corn starch, croscarmellose sodium, methylparaben, microcrystalline cellulose, pharmaceutical glaze, pharmaceutical ink, povidone, pregelatinized starch, propylparaben, sodium benzoate, sodium lauryl sulfate, stearic acid, sucrose, synthetic iron oxide, titanium dioxide, white wax

Advil Gel Caplets

colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C red no. 40, FD&C yellow no. 6, fractionated coconut oil, gelatin, glycerin, hypromellose, pharmaceutical ink, pregelatinized starch, propyl gallate, purified water, sodium lauryl sulfate, stearic acid, synthetic iron oxides, titanium dioxide, triacetin

Questions or comments?

call toll free **1-800-88-ADVIL**

PRINCIPAL DISPLAY PANEL – 100 Gel Caplet Bottle Carton

NDC 0573-0165-40

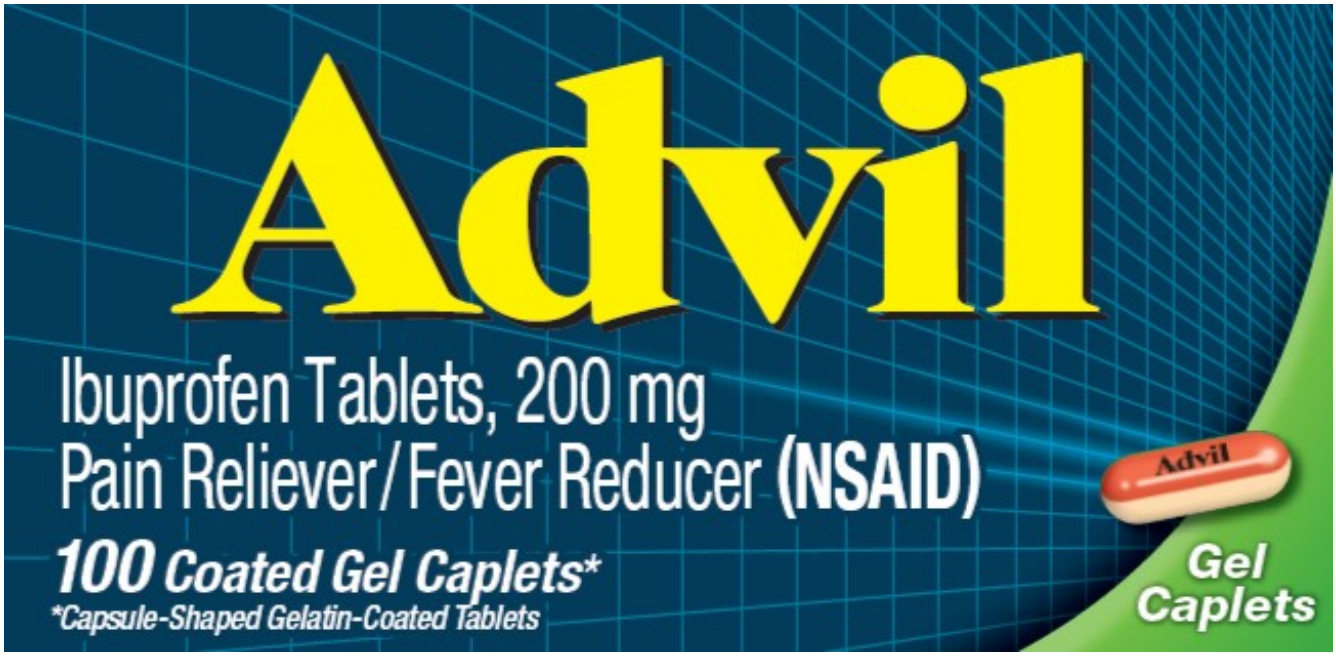
Advil

Ibuprofen Tablets, 200 mg
Pain Reliever / Fever Reducer (NSAID)

100 Coated Gel Caplets*
**Capsule-Shaped Gelatin-Coated Tablets*

Gel
Caplets

000067202 Front Carton



PRINCIPAL DISPLAY PANEL - 300 Tablet Bottle Label

Advil®
Ibuprofen Tablets, 200 mg
Pain Reliever/Fever Reducer (NSAID)

300 Coated Tablets

Tablets



PRINCIPAL DISPLAY PANEL - 115 Tablet Bottle Carton

15
FREE
TABLETS

Advil®
Ibuprofen Tablets, 200 mg
Pain Reliever/Fever Reducer (NSAID)

115
Coated Tablets

Tablets



PRINCIPAL DISPLAY PANEL - 225 Caplet Bottle Carton

25
FREE
CAPLETS

Advil®
Ibuprofen Tablets, 200 mg
Pain Reliever/Fever Reducer (NSAID)

225
Coated Caplets*
*Capsule-Shaped Tablets

Caplets



PRINCIPAL DISPLAY PANEL - 24 Tablet Bottle Carton

NDC 0573-0150-20

Advil
Ibuprofen Tablets, 200 mg
Pain Reliever/Fever Reducer (NSAID)

24 Coated Tablets

Tablets

000067199 Front Carton



PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Label

Advil®
Ibuprofen Tablets, 200 mg
Pain Reliever/Fever Reducer (NSAID)

100 Tablets

Tablets

READ AND KEEP CARTON FOR COMPLETE
WARNINGS AND INFORMATION

Do Not Use if seal under bottle cap imprinted with
"SEALED for YOUR PROTECTION" is broken or missing.



PRINCIPAL DISPLAY PANEL - 24 Caplet Bottle Carton

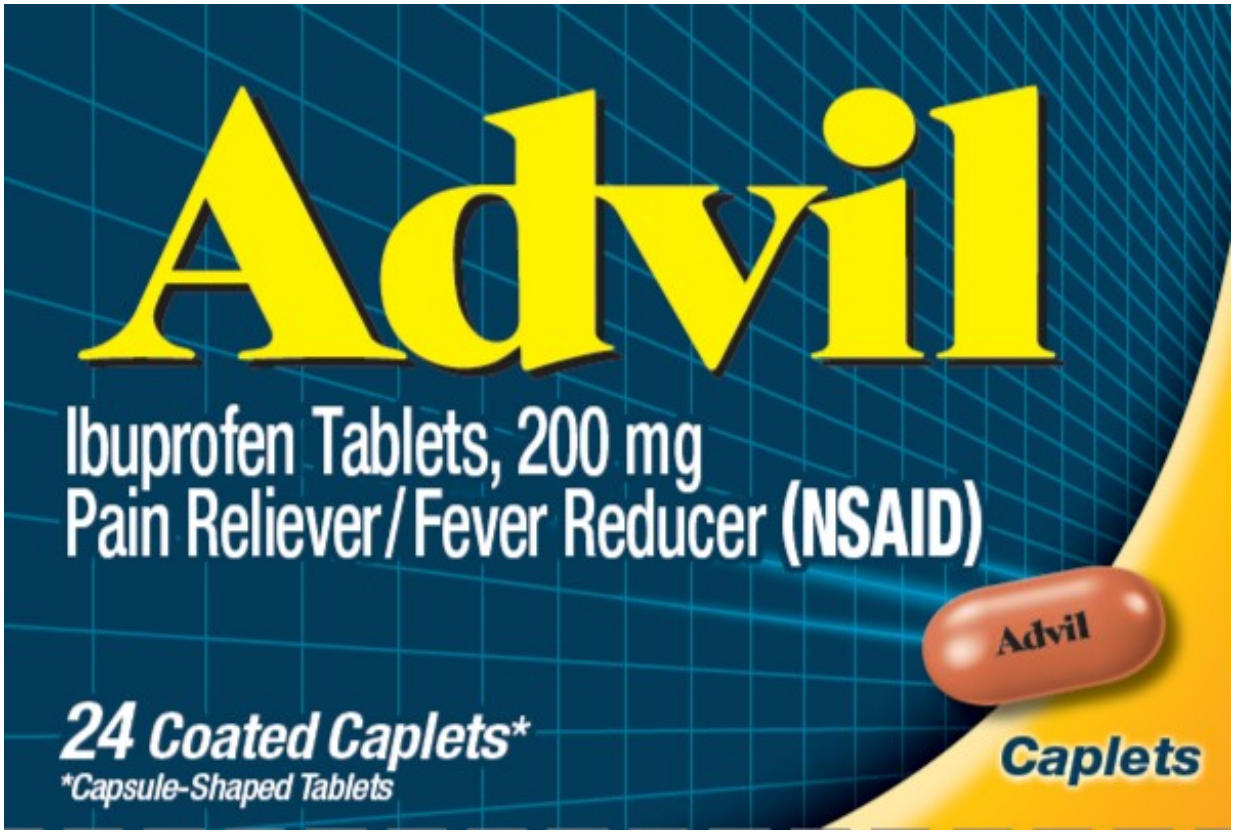
NDC 0573-0160-20

Advil
Ibuprofen Tablets, 200 mg
Pain Reliever/Fever Reducer (NSAID)

24 Coated Caplets*
*Capsule-Shaped Tablets

Caplets

000067201 Front Carton



Principal Display Panel - 225 Caplet Bottle Label

NDC 0573-1711-14

Advil®
Ibuprofen Tablets, 200 mg
Pain Reliever/Fever Reducer (NSAID)

225 Caplets

Caplets

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

PAA085439 Bottle Label



ADVIL

ibuprofen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0573-0165
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**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	BROWN (one side is brown while the other side is yellow)	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	Advil
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0165-20	1 in 1 CARTON	05/18/1984	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0573-0165-30	1 in 1 CARTON	05/18/1984	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0573-0165-40	1 in 1 CARTON	05/18/1984	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0573-0165-41	1 in 1 CARTON	05/18/1984	
4		125 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0573-0165-42	1 in 1 CARTON	05/18/1984	
5		150 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:0573-0165-31	1 in 1 CARTON	05/18/1984	
6		75 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:0573-0165-25	1 in 1 CARTON	05/18/1984	
7		36 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018989	05/18/1984	

ADVIL

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0573-0154
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
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WHITE WAX (UNII: 7G1J5DA97F)	
DIACETYLATED MONOGLYCERIDES (UNII: 5Z17386USF)	

Product Characteristics

Color	BROWN (pinkish brown)	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	Advil
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0154-35	1 in 1 CARTON	05/18/1984	
1		150 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0573-0154-75	1 in 1 CARTON	05/18/1984	
2		200 in 1 BOTTLE; Type 0: Not a Combination Product		

3	NDC:0573-0154-17	3000 in 1 CASE	05/18/1984	
3		2 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:0573-0154-89	50 in 1 CASE	05/18/1984	
4		2 in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:0573-0154-84	1 in 1 CARTON	05/18/1984	
5		225 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:0573-0154-98	300 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/1984	
7	NDC:0573-0154-16	3 in 1 CARTON	05/18/1984	
7		2 in 1 POUCH; Type 0: Not a Combination Product		
8	NDC:0573-0154-60	360 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/1984	
9	NDC:0573-0154-59	1 in 1 CARTON	05/18/1984	
9		200 in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:0573-0154-21	200 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018989	05/18/1984	

ADVIL

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0573-0151
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
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

METHYLPARABEN (UNII: A2I8C7HI9T)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WHITE WAX (UNII: 7G1J5DA97F)	
DIACETYLATED MONOGLYCERIDES (UNII: 5Z17386USF)	

Product Characteristics

Color	BROWN (pinkish brown)	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	Advil
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0151-12	10 in 1 VIAL; Type 0: Not a Combination Product	05/18/1984	
2	NDC:0573-0151-13	3 in 1 PACKAGE	05/18/1984	
2		10 in 1 VIAL; Type 0: Not a Combination Product		
3	NDC:0573-0151-10	10 in 1 PACKAGE	05/18/1984	
3		10 in 1 VIAL; Type 0: Not a Combination Product		
4	NDC:0573-0151-21	1 in 1 CARTON	05/18/1984	
4		36 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0573-0151-20	2 in 1 PACKAGE	05/18/1984	
5		10 in 1 VIAL; Type 0: Not a Combination Product		
6	NDC:0573-0151-48	2 in 1 PACKAGE	05/18/1984	
6		1 in 1 CARTON		
6		100 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:0573-0151-30	1 in 1 CARTON	05/18/1984	
7		130 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:0573-0151-05	1 in 1 CARTON	05/18/1984	

8		115 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018989	05/18/1984	

ADVIL

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0573-0161
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
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WHITE WAX (UNII: 7G1J5DA97F)	
DIACETYLATED MONOGLYCERIDES (UNII: 5Z17386USF)	

Product Characteristics

Color	BROWN (pinkish brown)	**Score**	no score
Shape	OVAL	**Size**	15mm
Flavor		**Imprint Code**	Advil

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0161-35	1 in 1 CARTON	05/18/1984	
1		150 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0573-0161-51	1 in 1 CARTON	05/18/1984	
2		200 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0573-0161-85	1 in 1 CARTON	05/18/1984	
3		225 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0573-0161-65	65 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018989	05/18/1984	

ADVIL

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0573-0166
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	BROWN (one side is brown while the other side is yellow)	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	Advil
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0166-51	1 in 1 CARTON	05/18/1984	
1		200 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0573-0166-85	225 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/1984	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018989	05/18/1984	

ADVIL

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0573-0150
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
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WHITE WAX (UNII: 7G1J5DA97F)	
DIACETYLATED MONOGLYCERIDES (UNII: 5Z17386USF)	

Product Characteristics

Color	BROWN (pinkish brown)	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	Advil
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0150-20	1 in 1 CARTON	05/18/1984	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0573-0150-30	1 in 1 CARTON	05/18/1984	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0573-0150-40	1 in 1 CARTON	05/18/1984	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0573-0150-31	1 in 1 CARTON	05/18/1984	
4		75 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0573-0150-32	1 in 1 CARTON	05/18/1984	
5		60 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:0573-0150-41	1 in 1 CARTON	05/18/1984	
6		125 in 1 BOTTLE; Type 0: Not a Combination		

6		Product		
7	NDC:0573-0150-42	1 in 1 CARTON	05/18/1984	
7		150 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018989	05/18/1984	

ADVIL

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0573-0160
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
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WHITE WAX (UNII: 7G1J5DA97F)	
DIACETYLATED MONOGLYCERIDES (UNII: 5Z17386USF)	

Product Characteristics

Color	BROWN (pinkish brown)	**Score**	no score

Shape	OVAL	**Size**	15mm
Flavor		**Imprint Code**	Advil
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0160-20	1 in 1 CARTON	05/18/1984	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0573-0160-30	1 in 1 CARTON	05/18/1984	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0573-0160-40	1 in 1 CARTON	05/18/1984	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0573-0160-25	1 in 1 CARTON	05/18/1984	
4		36 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0573-0160-31	1 in 1 CARTON	05/18/1984	
5		75 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:0573-0160-41	1 in 1 CARTON	05/18/1984	
6		125 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:0573-0160-42	1 in 1 CARTON	05/18/1984	
7		150 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:0573-0160-17	1 in 1 CARTON	05/18/1984	
8		115 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018989	05/18/1984	

ADVIL

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0573-1711

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
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WHITE WAX (UNII: 7G1J5DA97F)	
DIACETYLATED MONOGLYCERIDES (UNII: 5Z17386USF)	

Product Characteristics

Color	BROWN (pinkish brown)	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	Advil
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-1711-14	1 in 1 CARTON	05/18/1984	
1		225 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018989	05/18/1984	

Labeler - Haleon US Holdings LLC (079944263)

Establishment

Name	Address	ID/FEI	Business Operations
PF Consumer Healthcare B.V. (Puerto Rico Operations) LLC		118346012	ANALYSIS(0573-0150, 0573-0151, 0573-0154, 0573-0160, 0573-0161, 0573-0165, 0573-0166, 0573-1711) , LABEL(0573-0150, 0573-0151, 0573-0154, 0573-0160, 0573-0161, 0573-0165, 0573-0166, 0573-1711) , MANUFACTURE(0573-0150, 0573-0151, 0573-0154, 0573-0160, 0573-0161, 0573-0165, 0573-0166, 0573-1711) , PACK(0573-0150, 0573-0151, 0573-0154, 0573-0160, 0573-0161, 0573-0165, 0573-0166, 0573-1711)

Revised: 1/2024 Haleon US Holdings LLC