ADVIL- ibuprofen sodium tablet, coated
Wyeth Consumer Healthcare LLC
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ADVIL
ibuprofen sodium tablet, coated

Drug Facts

Active ingredient (in each tablet)
Ibuprofen 200 mg (provided as ibuprofen sodium 256 mg) (NSAID)¹

¹ 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 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 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 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.

**Directions**
- 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

Other information

- each tablet contains: sodium 22 mg
- 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

acesulfame potassium, caramel color, carnauba wax, colloidal silicon dioxide, copovidone, ferric oxide, hypromellose, mannitol, medium-chain triglycerides, microcrystalline cellulose, natural and artificial flavor, pharmaceutical ink, polyethylene glycol, propylene glycol, sodium lauryl sulfate, sucralose, titanium dioxide

Questions or comments?

Call weekdays 9 AM to 5 PM EST at 1-800-88-ADVIL

For most recent product information, visit www.Advil.com

Pfizer, Madison, NJ 07940 USA

PRINCIPAL DISPLAY PANEL - 80 Tablet Bottle Label

Advil®

Ibuprofen Tablets, 200 mg
(Provided as Ibuprofen Sodium 256 mg)

Pain Reliever / Fever Reducer (NSAID)

FILM-COATED
IBUPROFEN
SODIUM

80 Tablets

Questions or comments?

Call weekdays 9 AM to 5 PM EST at 1-800-88-ADVIL

For most recent product information, visit www.Advil.com

Pfizer, Madison, NJ 07940 USA

PRINCIPAL DISPLAY PANEL - 80 Tablet Bottle Carton

Advil®
FILM-COATED
IBUPROFEN
SODIUM

Ibuprofen Tablets, 200 mg
(Provided as Ibuprofen Sodium 256 mg)
Pain Reliever / Fever Reducer (NSAID)

Tablets
80 Tablets
Advil®
Ibuprofen Tablets, 200 mg
(Provided as Ibuprofen Sodium 256 mg)
Pain Reliever / Fever Reducer (NSAID)
FILM-COATED
IBUPROFEN
SODIUM
100 Tablets
80+20 FREE Tablets

Do Not Use If Seal Under Bottle Cap Is Imprinted With
"SEALED FOR YOUR PROTECTION" Is Broken Or Missing.

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION.

Close
- temporarily relieves minor aches and pains due to headache, muscular aches, minor arthritis, the common cold, backache, toothache, minor pain of arthritis. 
- temporarily reduces fever

Warnings
- Ask your doctor before use if you are pregnant, under a doctor's care for a serious condition, age 60 or over, taking any other drug or have stomach problems.
- This product 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. Do not use this product if you have ever had an allergic reaction to any pain reliever/fever reducer.
- Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause 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 daily while using this product
- take more or for a longer time than directed

PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Carton

Advil®
20 FREE TABLETS
Ibuprofen Tablets, 200 mg
(Provided as Ibuprofen Sodium 256 mg)
Pain Reliever / Fever Reducer (NSAID)
FILM-COATED
IBUPROFEN
SODIUM
Tablets
100 Tablets
ADVIL
ibuprofen sodium tablet, coated

Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
<th>Item Code (Source)</th>
<th>NDC:0573-0133</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route of Administration</td>
<td>ORAL</td>
<td></td>
<td></td>
</tr>
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</table>

Active Ingredient/Active Moiety
### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBUPROFEN SODIUM</td>
<td>(UNII: RM1CE97Z4N)</td>
<td>IBUPROFEN SODIUM</td>
</tr>
<tr>
<td>IBUPROFEN SODIUM</td>
<td>(UNII: WK2XYI10QM)</td>
<td>256 mg</td>
</tr>
</tbody>
</table>

### Product Characteristics

- **Color**: BROWN (beige)
- **Score**: no score
- **Shape**: ROUND
- **Size**: 10 mm
- **Flavor**: Imprint Code: Advil; asymmetrical; underline
- **Contains**:

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0573-0133-20</td>
<td>1 in 1 CARTON</td>
<td>07/08/2013</td>
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<td>2</td>
<td>NDC:0573-0133-40</td>
<td>1 in 1 CARTON</td>
<td>07/08/2013</td>
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<td>3</td>
<td>NDC:0573-0133-80</td>
<td>1 in 1 CARTON</td>
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<td>NDC:0573-0133-02</td>
<td>50 in 1 TRAY</td>
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<td>5</td>
<td>NDC:0573-0133-04</td>
<td>2 in 1 BLISTER PACK</td>
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<td>9</td>
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<td>NDC</td>
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<tr>
<td>0573-0133-41</td>
<td>120 in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>1 in 1 CARTON</td>
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<tr>
<td>0573-0133-91</td>
<td>40 in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>1 in 1 CARTON</td>
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<tr>
<td>0573-0133-01</td>
<td>180 in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>3000 in 1 CASE</td>
<td>08/11/2014</td>
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<tr>
<td>0573-0134</td>
<td>2 in 1 PACKET; Type 0: Not a Combination Product</td>
<td>3000 in 1 CASE</td>
<td>08/11/2014</td>
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</tr>
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<tbody>
<tr>
<td>NDA</td>
<td>NDA201803</td>
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**ADVIL**

ibuprofen sodium tablet, coated

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<tr>
<td>ACESULFAME POTASSIUM (UNII: 23OY73Q5G9)</td>
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</tr>
<tr>
<td>CARAMEL (UNII: T9D99G2B1R)</td>
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<tr>
<td>CARNAUBA WAX (UNII: R12CBM0EIZ)</td>
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</tr>
<tr>
<td>SILICON DIOXIDE (UNII: ETJ7Z6XBU4)</td>
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<tr>
<td>COPOVIDONE K25-31 (UNII: D9C330MD8B)</td>
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<tr>
<td>FERRIC OXIDE RED (UNII: 1K09F3G675)</td>
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<tr>
<td>HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)</td>
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<tr>
<td>MANNITOL (UNII: 3OWL53L36A)</td>
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<tr>
<td>MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)</td>
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<tr>
<td>MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)</td>
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<tr>
<td>POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05D1W)</td>
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<tr>
<td>PROPYLENE GLYCOL (UNII: 6DC9Q167V3)</td>
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<td>SODIUM LAURYL SULFATE (UNII: 368GB5141J)</td>
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<tr>
<td>SUCRALOSE (UNII: 96K6UQ3ZD4)</td>
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<td>TITANIUM DIOXIDE (UNII: 15FX9V2JP)</td>
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<tr>
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<td>OVAL</td>
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<td>15mm</td>
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<td>Flavor</td>
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<td>Advil;asymmetrical;underline</td>
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**Labeler** - Wyeth Consumer Healthcare LLC (828831730)

**Registrant** - Pfizer Inc (113480771)

**Establishment**

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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</thead>
<tbody>
<tr>
<td>Wyeth Pharmaceuticals Company</td>
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<td>829390975</td>
<td>ANALYSIS(0573-0133, 0573-0134), LABEL(0573-0133, 0573-0134), MANUFACTURE(0573-0133, 0573-0134), PACK(0573-0133, 0573-0134)</td>
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Revised: 6/2019