

## **IBUPROFEN- ibuprofen tablet** **HART Health**

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**IBUPROFEN**

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

**Purpose:** Pain Reliever / Fever Reducer

**Uses:** Temporarily relieves minor aches and pains due to

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

Temporarily reduces fever

### **Warnings:**

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

- hives
- rash
- shock
- facial swelling
- asthma (wheezing)
- skin reddening
- blisters

**Stomach bleeding warning:** This product contains an 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 more or for a longer time than directed
- take a blood thinning (anticoagulant) or steroid drug
- have 3 or more alcoholic drinks every day while using this product
- take other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

### **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 a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic

### **Ask a doctor or pharmacist before use if you**

- take any other drug containing an NSAID
- take a blood thinning (anticoagulant) or steroid drug
- take aspirin for heart attack or stroke (ibuprofen may decrease the benefit if aspirin)
- are under a doctor's care for any serious condition

### **When using this product**

- take with food or milk if stomach upset occurs
- long term continuous use may increase the risk of heart attack or stroke

### **Stop use and ask a doctor if**

- an allergic reaction occurs, seek medical help right away
- fever gets worse or lasts more than 3 days
- pain gets worse or lasts more than 10 days
- redness or swelling is present in the painful area
- new symptoms occur
- you have any of the following signs of stomach bleeding: feel faint, vomit blood, have bloody or black stools, or stomach pain that does not get better

**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.

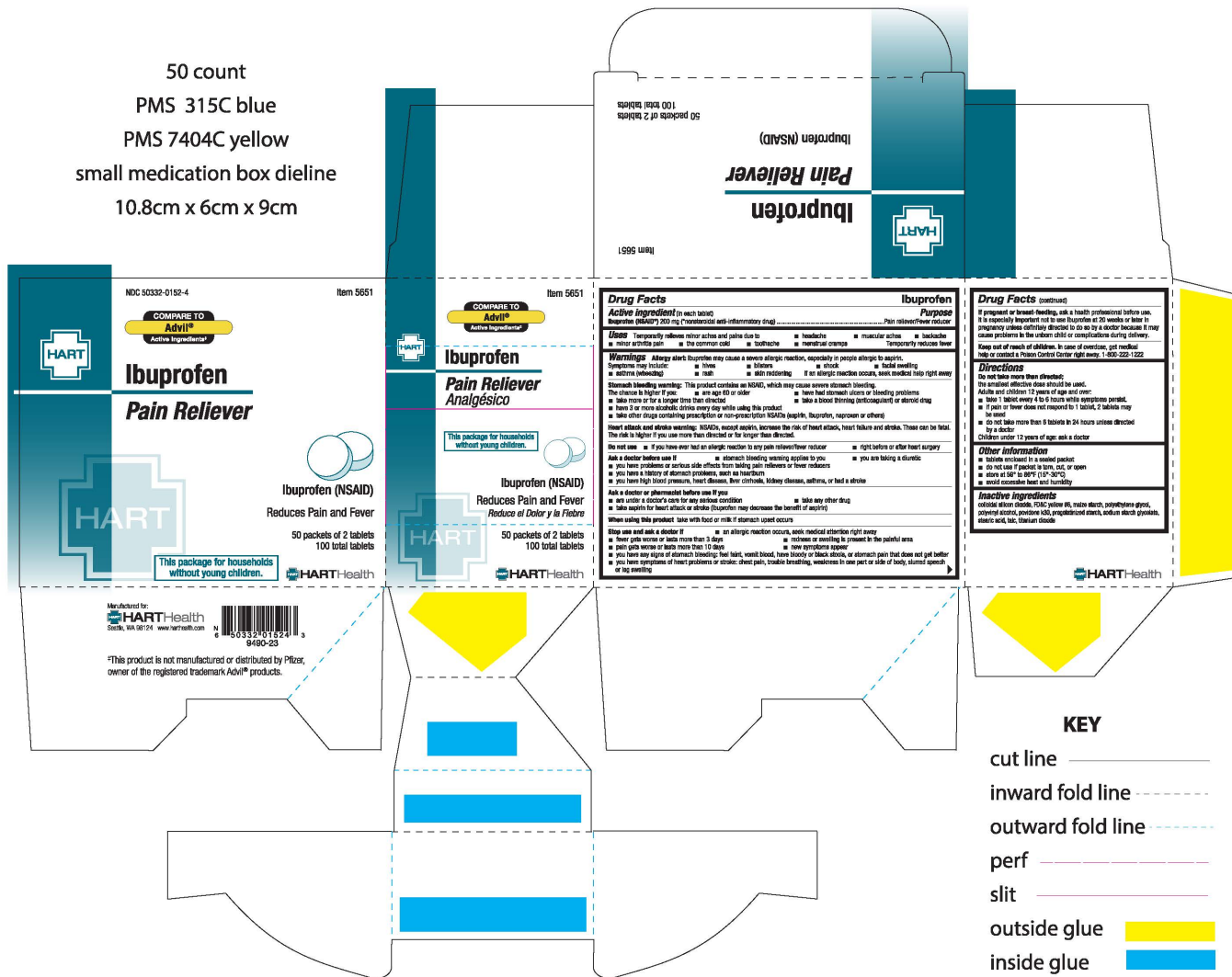
Adults and children 12 years of age and over:

- 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 take more than 6 tablets in 24 hours unless directed by a doctor

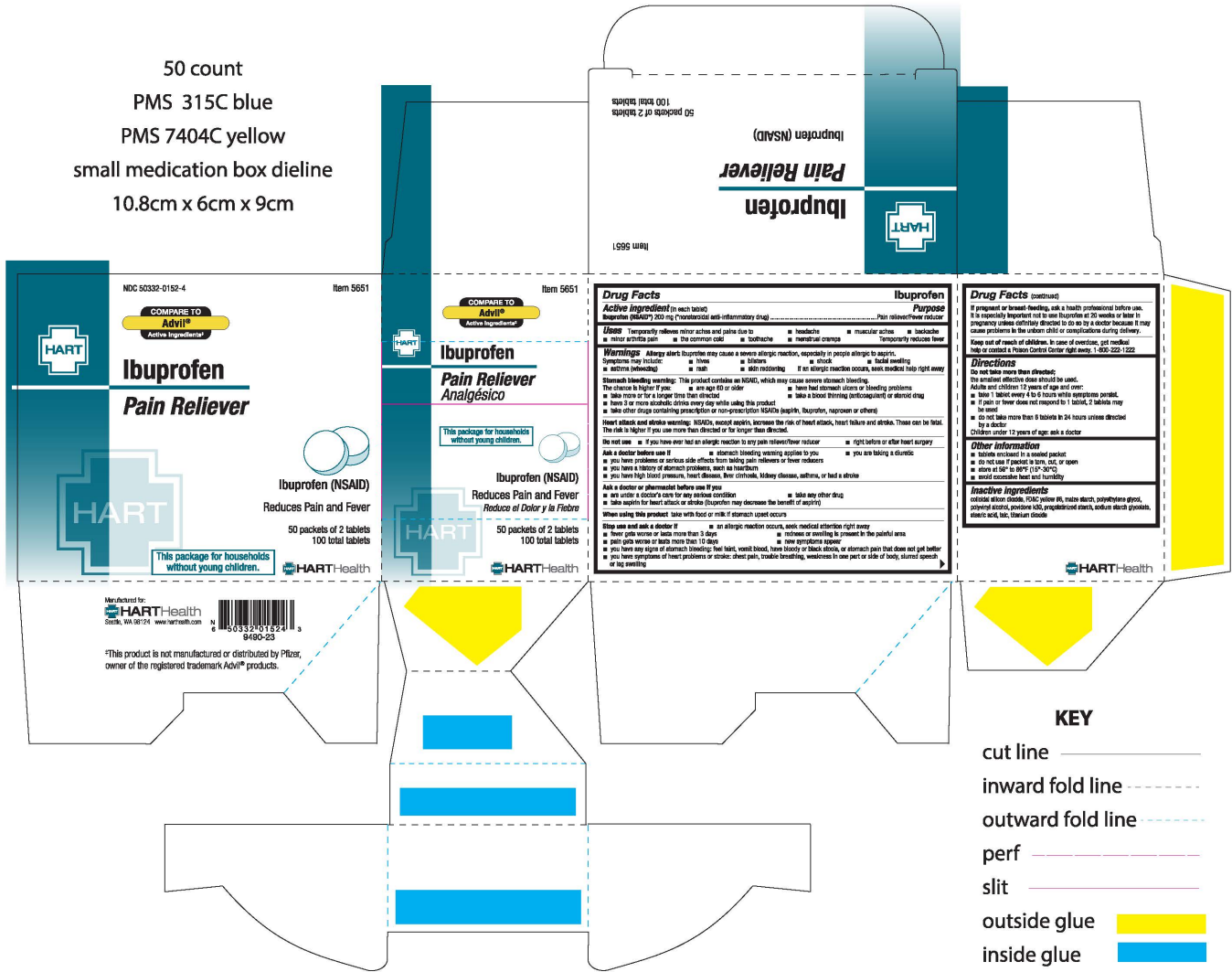
Children under 12 years of age: ask a doctor

Inactive Ingredients: Colloidal Silicon Dioxide, Corn Starch\*, Croscarmellose Sodium\*, Hypromellose\*, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol\*, Polyvinyl Alcohol\*, Pregelatinized Starch, Red Iron Oxide, Sodium Starch Glycolate\*, Talc, Titanium Dioxide, Triacetin\*.

\*Contains one or more of these ingredients.



50 count  
 PMS 315C blue  
 PMS 7404C yellow  
 small medication box dieline  
 10.8cm x 6cm x 9cm



NDC 50332-0152-4

Item 5651

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COMPARE TO  
**Advil®**  
 Active Ingredient\*

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 Active Ingredient\*

**Ibuprofen**  
**Pain Reliever**

**Ibuprofen**  
**Pain Reliever**  
**Analgésico**

**Ibuprofen (NSAID)**  
 Reduces Pain and Fever  
 50 packets of 2 tablets  
 100 total tablets

**Ibuprofen (NSAID)**  
 Reduces Pain and Fever  
 Reduco el Dolor y la Fiebre  
 50 packets of 2 tablets  
 100 total tablets

Manufactured for  
**HART-Health**  
 Seattle, WA 98124 www.hart-health.com  
 N 50332-0152-4  
 9490-23

\*This product is not manufactured or distributed by Pfizer, owner of the registered trademark Advil® products.

**Drug Facts**

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

**Warnings** Temporarily relieve minor aches and pains due to:  
 ■ minor arthritis ■ the common cold ■ headache ■ muscular aches ■ backache  
 ■ minor arthritis pain ■ the common cold ■ headache ■ menstrual cramps ■ temporary reduced fever

**Directions** Temporarily relieve minor aches and pains due to:  
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**Other Information** Temporarily relieve minor aches and pains due to:  
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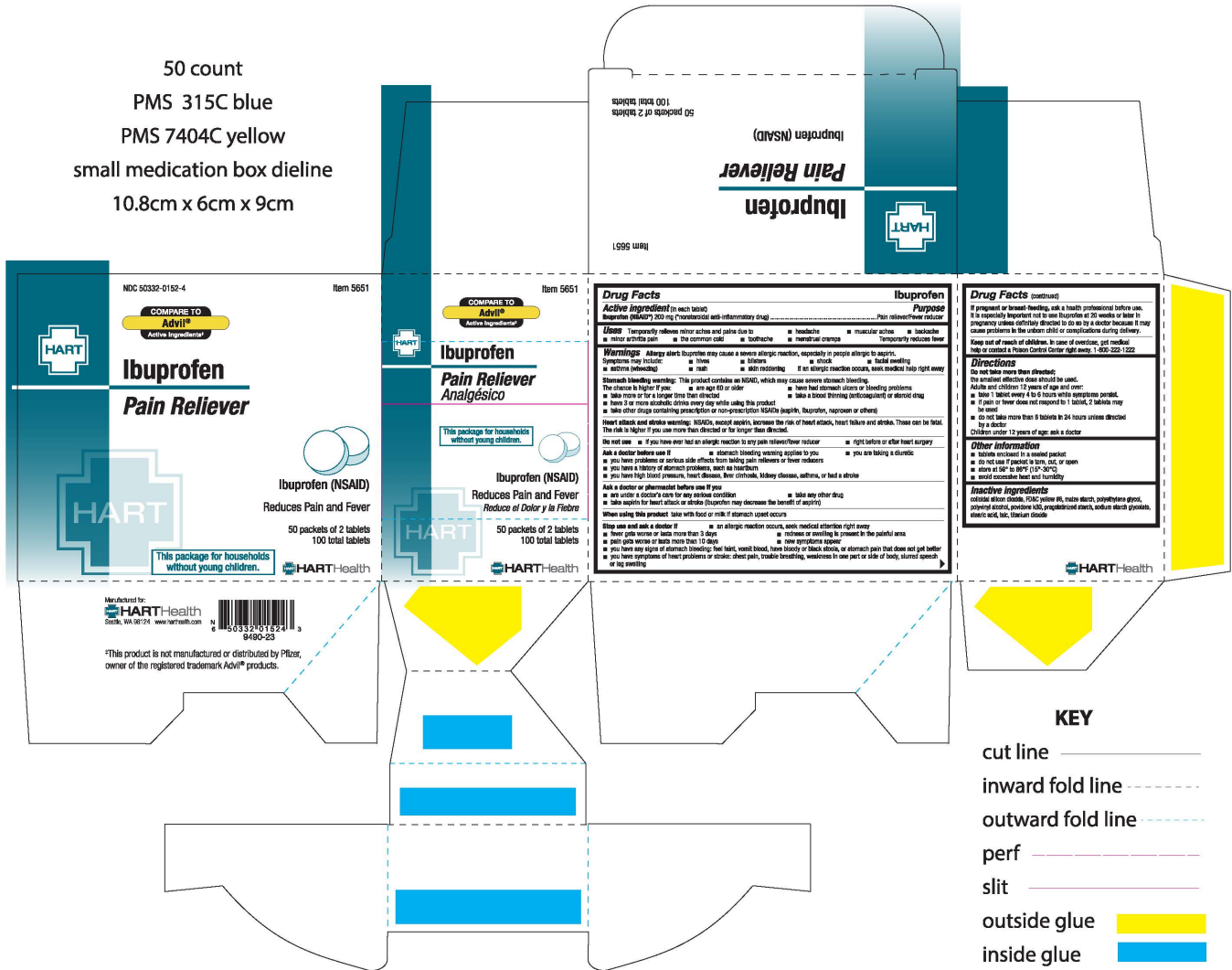
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**KEY**

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- perf \_\_\_\_\_
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- outside glue
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**IBUPROFEN**

ibuprofen tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50332-0152
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	

<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

### Product Characteristics

<b>Color</b>	brown	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	G;2
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50332-0152-4	50 in 1 BOX, UNIT-DOSE	01/01/2023	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:50332-0152-7	125 in 1 BOX, UNIT-DOSE	01/01/2023	
2		2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:50332-0152-8	250 in 1 BOX, UNIT-DOSE	01/01/2023	
3		2 in 1 PACKET; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M	01/01/2023	

**Labeler** - HART Health (069560969)