

**AEROTAB IBUPROFEN- ibuprofen tablet tablet, coated**  
**Aero Healthcare**

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**ACTIVE INGREDIENT**

***Drug Facts***

**Active Ingredient (in each tablet)**

Ibuprofen 200 mg (NSAID)\*

**PURPOSE**

**Purpose**

Ibuprofen 200 mg (NSAID)\*.....Pain Reliever Fever Reducer

\*nonsteroidal anti-inflammatory drug

**INDICATIONS & USAGE**

**Uses:**

Temporarily Relieves minor aches and pains  
due to:

- Headache, toothaches, backache, menstrual cramps, the common cold,
- muscular aches, minor pain of arthritis

Temporarily reduces fever

**WARNINGS**

**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 a nonsteroidal anti-inflammatory drug (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 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, 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**

### **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, 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 a heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

## **WHEN USING THIS PRODUCT**

When using this product take with food or milk if stomach upset occurs

## **STOP USE AND ASK A DOCTOR**

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
- stomach pain that does not get better
- 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 last more than 10 days
- fever gets worse or last more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

## **IF PREGNANT OR BREAST FEEDING**

**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**

**Keep out of reach of children.**

**Overdose warning:** In case of overdose, seek medical help or contact a Poison Control Center (1-800-222-1222) right away.

Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

## **DOSAGE & ADMINISTRATION**

**Directions:** take only as directed - see Overdose warning.

**Adults and children 12 years of age and older** 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.** Do not take more than directed (see overdose warning). The smallest effective dose should be used.

## **OTHER INFORMATION**

### **Other Information**

Tamper evident. Do not use if packet is torn, cut or opened. Store between 20C to 25C (68F to 77F). Read all warnings and directions before use

## **INACTIVE INGREDIENTS**

### **Inactive Ingredients:**

corn starch, hypromellose, red iron oxide, magnesium stearate, microcrystalline cellulose, pregelatinized starch, silicon dioxide, sodium starch glycolate, talc, titanium dioxide, triacetin

## **PRODUCT PACKAGE**

### **AeroTab**

Ibuprofen USP 200mg

Anti-inflammatory

Fever reducer

Pain reliever

250

2 per packet



CODE: V1 ATIB50US BX    DATE: 09/08/2020    DIMENSIONS: 110mm W x 90mm H x 65mm D

AERO HEALTHCARE – US PACKAGING PROGRAM BATCH 1 | PART THREE (REVISIONS)



CODE: V2.ATB100US.BX    DATE: 06/17/2019    DIMENSIONS: 110mm W x 90mm H x 65mm D

AERO HEALTHCARE – US PACKAGING PROGRAM BATCH 1 | PART THREE (REVISIONS)



**Drug Facts**

**ACTIVE INGREDIENTS (per tablet)** **PURPOSE**  
 Ibuprofen USP, 200mg Pain Reliever / Fever Reducer  
 \*nonsteroidal anti-inflammatory drug

**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 redness ● rash ● blistering. If an allergic reaction occurs stop use and seek medical help right away. Stomach bleeding warning: this product contains a nonsteroidal anti-inflammatory drug (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 ● 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:** ● 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 a heart attack or stroke, because ibuprofen may decrease the 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 ● stomach pain that does not get better ● symptoms of heart problems or stroke ● chest pain ● trouble breathing ● weakness in one part or side of body ● slurred speech ● tingling ● 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.

**IBUPROFEN**

ibuprofen USP 200mg

250

Anti-inflammatory  
 Fever reducer  
 Pain reliever

250 | 2 per packet

**IBUPROFEN**

ibuprofen USP 200mg

250

Anti-inflammatory  
 Fever reducer  
 Pain reliever

250  
2 per packet

**Drug Facts (continued)**

**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.**  
**Overdose warning:** In case of overdose, seek medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**DIRECTIONS** take only as directed — see Overdose warning. **Adults and children 12 years of age and older** 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. Do not take more than directed (see overdose warning). The smallest effective dose should be used.

**OTHER INFORMATION** Tamper evident. Do not use if packet is torn, cut or opened. Store between 20°C to 25 (68°F to 77°F). Read all warnings and directions before use.

**INACTIVE INGREDIENTS** Corn starch, hypromellose, iron oxide red, magnesium stearate, microcrystalline cellulose, pregelatinized starch, silicon dioxide, sodium starch glycolate, talc, titanium dioxide, triacetin.



Lot # 1000  
 0528141  
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**AERO** HEALTHCARE  
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Manufactured for AERO HEALTHCARE  
 US Valley Cottage, NY 10989  
 www.aerohealthcare.us.com  
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CODE: VI.A18250 BX  
 DATE: 12/06/2019  
 DIMENSIONS: 114mm W x 129.5mm H x 81.28mm D



## IBUPROFEN

**ACTIVE INGREDIENTS (per tablet)**

Ibuprofen 200mg (NSAID) ..... Pain reliever/Fever reducer

\* nonsteroidal anti-inflammatory drug

**Purpose**

**2 Tablets Per Packet**

**CODE: ATIB001**

Tamper-evident packaging. Do not use if packet is torn or open.

**WARNINGS:** This product contains nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you: ■ have had stomach ulcers ■ or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ are age 60 or older ■ have 3 or more alcoholic drinks every day while using this product ■ take with other drugs containing an NSAID ■ take more or for longer than directed ■ **If pregnant or breast feeding**, ask a health professional before use. **KEEP OUT OF REACH OF CHILDREN.** In case of overdose, get medical help or contact a Poison Control Center right away. **DIRECTIONS:** Adults Only: 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, but do not exceed 6 tablets in 24 hours, unless directed by a doctor. **See box for complete product information.**  
Mfg. for: Aero Healthcare, Valley Cottage, NY 10989 ATIB001V2

# AEROTAB IBUPROFEN

ibuprofen tablet tablet, coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55305-133
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg in 1000 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POLYETHYLENE GLYCOL 1000</b> (UNII: U076Q6Q621)	
<b>POLYVINYL ALCOHOL (100000 MW)</b> (UNII: 949E52Z6MY)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	

## 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>	
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:55305-133-02	25 in 1 BOX	01/01/2018	
1	NDC:55305-133-01	2 mg in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:55305-133-03	25 in 1 BOX	01/01/2018	
2	NDC:55305-133-01	2 mg in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:55305-133-04	50 in 1 BOX	01/01/2018	
3	NDC:55305-133-01	2 mg in 1 PACKET; Type 0: Not a Combination Product		



4	NDC:55305-133-05	125 in 1 BOX	01/01/2018	
4	NDC:55305-133-01	2 mg in 1 PACKET; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091239	01/01/2018	

**Labeler** - Aero Healthcare (008186174)

Revised: 4/2022

Aero Healthcare