

AEROTAB IBUPROFEN- ibuprofen tablet tablet, coated
Aero Healthcare

AeroTab Ibuprofen Tablets

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

Ibuprofen Package

AeroTab

Ibuprofen USP 200mg

Anti-inflammatory

Fever reducer

Pain reliever

250

2 per packet



AERO HEALTHCARE
 WE MAKE IT BETTER

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)

AEROTAB IBUPROFEN ibuprofen tablet tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55305-133
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)		IBUPROFEN	200 mg in 1000 mg

Inactive Ingredients

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

Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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)