

ARAMARK IBUPROFEN- ibuprofen tablet
Western First Aid Safety DBA Aramark

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Aramark Ibuprofen

Drug Facts

Active Ingredient (in each tablet)

Ibuprofen 200 mg (**NSAID**)*

Purpose

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

*nonsteroidal anti-inflammatory drug

Uses:

Temporarily Relieves minor aches and pains due to:

- Headache, toothaches, 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

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 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

Do not use:

- if you have ever had an allergic reaction to any other pain
- reliever/fever reducer
- right before or after heart surgery

- if you have ever had an allergic reaction to this product or any of its ingredients

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, or asthma
- 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 the benefit of aspirin
- taking the blood thinning drug Warfarin

When using this product:

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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
 - 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 occur

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:

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:

colloidal silicon dioxide, corn starch, sodium starch glycollate, hypromellose, lactose monohydrate, povidone, pregelatinized corn starch, red iron oxide, sodium starch glycolate, steric acid, talc, titanium dioxide, triacetin, purified water

Product Package

aramark

100 TABLETS PER BOX

Part # 552R23

Ibuprofen

Anti-Inflammatory Fever Reducer

Compare active ingredient to:

ADVIL®

Registered Trademark of Pfizer Consumer Healthcare

Retain carton for complete product information

MANUFACTURED FOR:

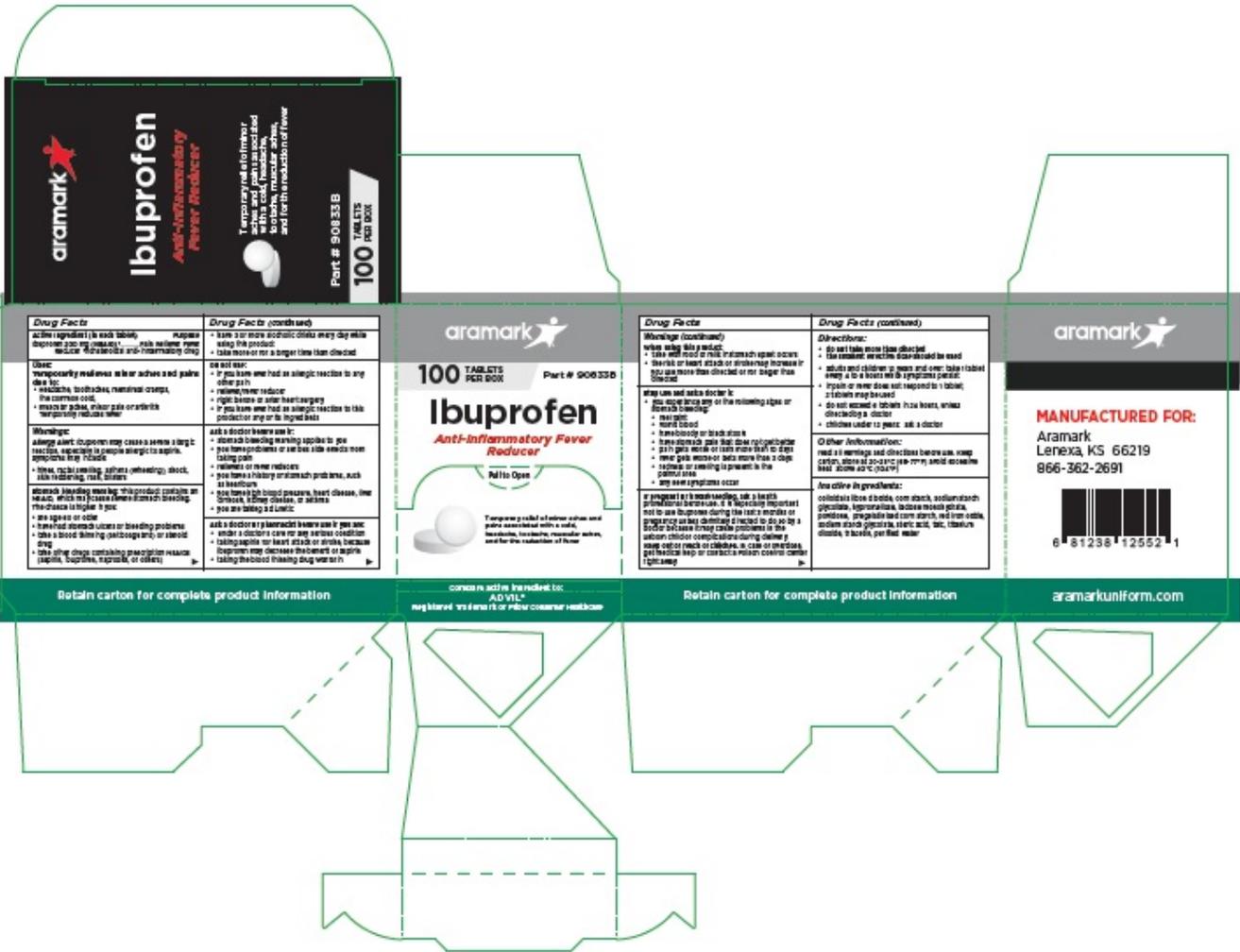
Aramark

Lenexa, KS 66219

(913) 269-9611

aramarkuniform.com

100 Tablet Box



250 Tablet Box



IBUPROFEN

Pain Reliever/Fever Reducer

2 Tablets

Active Ingredients Purpose

(In Each Tablet)

Ibuprofen (NSAID)*200 mg.....
Pain Reliever/Fever Reducer
*nonsteroidal anti-inflammatory drug

Uses: Temporarily relieves minor aches and pains due to:

- common cold • backache • headache
- arthritis • toothache • menstrual cramps • muscular aches

Warnings: 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 a blood thinning (anticoagulant) or steroid drug • take other drugs

Warnings (continued)

containing prescription or nonprescription NSAIDS (aspirin, ibuprofen, naproxen) • have 3 or more alcoholic drinks every day while using this product • take more or for a longer time than directed.

Keep out of reach of children.

Directions: Do not use more than directed. Adults and children 12 years of age and older: 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: Consult a doctor.

Other Information: Store at a controlled room temperature 15°-30° (59°-86°F). Tamper evident: Do not use packet if torn or cut.

Contact: Aramark Lenexa, KS 66219

FOR COMPLETE WARNINGS/CAUTIONS: SEE BOX

REV 3/2021

Made in USA

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ARAMARK IBUPROFEN

ibuprofen tablet

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:81238-0103 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM) | IBUPROFEN | 200 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |

| | |
|---|--|
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| POVIDONE (UNII: FZ989GH94E) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIACETIN (UNII: XHX3C3X673) | |
| WATER (UNII: 059QF0KO0R) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | white | Score | no score |
| Shape | ROUND | Size | 15mm |
| Flavor | | Imprint Code | G2 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:81238-0103-1 | 50 in 1 BOX | 05/14/2021 | |
| 1 | | 2 in 1 PACKET; Type 0: Not a Combination Product | | |
| 2 | NDC:81238-0103-2 | 125 in 1 BOX | 05/14/2021 | |
| 2 | | 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 not final | part343 | 05/14/2021 | |

Labeler - Western First Aid Safety DBA Aramark (043861524)

Registrant - Western First Aid Safety DBA Aramark (043861524)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|---------------------|
| Ultra Seal Corporation | | 085752004 | pack(81238-0103) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|-------------------------|
| Ultra Seal Corporation | | 944090448 | manufacture(81238-0103) |

