IBUPROFEN- ibuprofen tablet, film coated
A-S Medication Solutions

GC 941

Active ingredient (in each brown tablet)

Ibuprofen USP, 200 mg (NSAID)*
*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:

- shock
- hives
- facial swelling
- asthma (wheezing)
- 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
- the 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 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 - leg swelling
  - slurred speech - weakness in one part or side of body
- pain gets worse or lasts more than 10 days
- redness or swelling is present in the painful area
- fever gets worse or lasts more than 3 days
- any new symptoms occur

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in 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 (1-800-222-1222) right away.

Directions

- **do not use 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 take more than 6 tablets in 24 hours unless directed by a doctor
- children under 12 years: ask a doctor

Other information

- store between 20°-25°C (68°-77°F)
- avoid excessive heat 40°C (104°F)

Inactive ingredients

carnauba wax, colloidal silicon dioxide, cellulose, corn starch, hypromellose, lactose, magnesium stearate, polydextrose, PEG, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide.

Questions or comments?

Call 1-800-540-3765

HOW SUPPLIED

Product: 50090-5021

NDC: 50090-5021-0 50 TABLET, FILM COATED in a BOTTLE

NDC: 50090-5021-3 24 TABLET, FILM COATED in a BOTTLE

NDC: 50090-5021-8 100 TABLET, FILM COATED in a BOTTLE

IBUPROFEN

IBUPROFEN

ibuprofen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50090-5021(NDC:57896-941)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
STARCH, CORN (UNII: O8232NY3SJ)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	brown	**Score**	no score
Shape	ROUND	**Size**	10mm

Flavor		**Imprint Code**	44291
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-5021-0	50 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
2	NDC:50090-5021-3	24 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
3	NDC:50090-5021-8	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075010	01/01/2004	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-5021) , REPACK(50090-5021)

Revised: 11/2023 A-S Medication Solutions