

PAIN RELIEVER / FEVER REDUCER- ibuprofen tablet
Pioneer Life Sciences, LLC

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.

Pain Reliever / Fever Reducer

Active Ingredient

Ibuprofen 200 mg (NSAID)¹

1 - 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:

- 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 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

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 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 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
- weakness in one part or side of body
- slurred speech
- leg swelling

- 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

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

- **each tablet contains:** sodium 22mg
- read all product information before use.
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

INACTIVE INGREDIENTS

Pregelatinized Starch, Maize Starch, Sodium Starch Glycolate, Povidone K-30, Purified Water, Stearic Acid, Colloidal Silicon Dioxide, Opadry II 85F565026

QUESTIONS OR COMMENTS?

Call 1-732-698-5070 Monday through Friday 9AM-5PM EST or
www.pioneerlifesciences.com

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PRINCIPAL DISPLAY PANEL

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72090-002-01	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	05/18/2021	

Labeler - Pioneer Life Sciences, LLC (014092742)

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Pioneer Life Sciences, LLC