GOOD SENSE IBUPROFEN- ibuprofen tablet, film coated L. Perrigo Company

Perrigo Ibuprofen Drug Facts

Active ingredient (in each tablet)

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- headache
- muscular aches
- minor pain of arthritis
- toothache
- backache
- the common cold
- menstrual cramps
- 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 chances are 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 ibuprofen or any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- you have problems or serious side effects from taking pain relievers or fever reducers
- the stomach bleeding warning applies to you
- 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

- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under a doctor's care for any serious condition
- · 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 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 right away (1-800-222-1222).

Directions

- do not take more than directed
- the smallest effective dose should be used

adults and children 12 years 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

Other information

- read all warnings and directions before use
- store between 20-25°C (68-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)
- see end panel for lot number and expiration date

Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, iron oxide red, iron oxide yellow, microcrystalline cellulose, polyethylene glycol, polysorbate 80, stearic acid, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

TWIN PACK

 $\mathsf{GOODSENSE}_{\mathbb{R}}$

Tablets

See Revised Warning

Ibuprofen Tablets, 200 mg

Pain Reliever/Fever Reducer (NSAID)

100 Coated Tablets Compare to active ingredient of Advil® Ibuprofen Tablets



COLUMN CARDE TRANSPORT SAMELY (1-8 UU- 22 Z-1 Z ZZ.) Keep, auto frea da o f children. In case of uringdelivery. prodems in meuro an childor complications

later inpregnancy unless definitely directed to doso by adoctor because it may cause professional before use. It is e specially important not to use ibuprofen at 20 weeks or If pregnant or bre-ast-fe eding, ask a health

ma quàus akuub naus grbbegu ears luhring enth nithe eanq sig nillaw s nosean bea ■

m sturred speach metegeweiting monigets worse or tasts more trans 3d ays mover gets worse or tasts more trans. 3d ays ybod foe bis no me part or side of body

ning teetb gmintrænd eliduont 🔳 you have symptoms of he art problems or strok e.

ha vestomach pain that does not get better

to be drived on a sound the drived on a sound the drived on a sound the sound the sound on the ■ you experience any of the following signs of Stop use and as k a doctor if

■ tak ewith food ormilk if stomach up set occura Suborqsiff gnisuned W Entra Sany of the Grang

■ un dara. doctora care foran y serious condition ningsato Decause ibu profen may decrease this benefit ■ falking aspirin for heartaitack or atroke,

Ask a doctor or pharmacist before useif (panuguco) stast grud

lf an alle ngic reaction occurs, sho puse and seek medical halp right away.

alle rgic re action, especially inpeople allergic to aspirin. Symptoms may include:

Of 02 4 M Jr 889llA

[®]OgiTJ9¶ ya b atudintaid

GlutenFree

(NSAID) Fever Reducer Pain Reliever

Idblets, 200 mg uəjoidnqi

Important:Read all p to duct information beforeu sing Keep this pack age to rimportant in formation.

ш уоцеты тампу алішетіс

■ you have high blood pressure, heart dse ase SUCH 36 DESTRUCTION

Tever reducer

except asplin, increase fre iek of heart attack heart falure, and shoke. The se cambe fatal, The risk is high er if you use more fran disc be d ar fan diested. ■take more orfora longerfime than directed Heartattack and stroke warming:NSADs,

■ have 3 or more alcoholic dim ks every day while using this product

steroid drug take other drugs containing prescription or

stomach ble eding. The chance is higher if you

gund yacts (confuned)

liver cirh ceis, kichney disease, aethma, or had a stroke

■ you have a history of stomach problems, montal pain relie versor fever reduces a from taken pain relie versor fever reduced so your montal set for warm of set for montal set for mo ■ you have problems or serious sideeffects Ask a doctor before use if

Tright before or after heart surgery

ib up to famor any other parin milever/ a if you have everhad an alergic reaction to esu ton of

n omprescription NSAIDs [aspirin, ibu profen, n approxen, orothers]

smeldorų no (insugeccining (anticoagulant) or no (insugeccining (anticoagulant) or

m have hardstornar hulcers or bleeding

Shomach bleeding warming: This product contains an MSAD, which may cause seven

E temporantly reduces tever

edindre tonissy ranim =

cor eu bismis quin USGS temporarily relieves minoradas

Pronteroidal arti-inflammatory drug

(in each tablet) жейле індтедіві səso dıny

Mamings Mamings

(pənuguco) stasi find

DO NOT USE IFPRINTED SEAL UNDER CAP IS ERROKEN OR MIS SING

enetaid III US 12

Shorts =

gnine bben nisks =

eviri∎ Emillewelsions'∎

(g nizae ńw) sm rhas ■

admanalo tampa ■ backadre entacrito di m

as ricas ratuce um 🔳 apapea |

Pain reliever/ lbuprofen 200 mg (NSAID)?

Spel gund

GOODSENSE.

Tablets

NDC 0113-0604-82

See Revised Warning

lbuprofen Tablets, 200 mg

Pain Reliever/Fever Reducer (NSAID)

Compare to active in gredient of Advil® ibuprofen Tablets

100 Coated Tablets

See Revised Warning

GOODSENSE. Tablets

lbuprofen Tablets, 200 mg

Pain Reliever/Fever Reducer (NSAID)















GOOD SENSE IBUPROFEN

ibuprofen tablet, film coated

Drodin	ct Into	rmation
riouu	94 1110	HIHALIVII

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0113-0604
--------------	----------------	--------------------	---------------

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI100M) (IBUPROFEN - UNII:WK2XYI100M)	IBUPROFEN	200 ma

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BROWN	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:0113-0604- 52	10 in 1 VIAL; Type 0: Not a Combination Product	04/15/1991	05/01/2021		
2	NDC:0113-0604- 62	1 in 1 CARTON	05/04/1992			
2		24 in 1 BOTTLE; Type 0: Not a Combination Product				

3	NDC:0113-0604-71	1 in 1 CARTON	09/15/1989	
3		50 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0113-0604- 76	1 in 1 CARTON	06/15/1991	06/20/2019
4		120 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0113-0604- 78	1 in 1 CARTON	09/15/1989	
5		100 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:0113-0604- 90	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/1993	
7	NDC:0113-0604- 93	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/31/2007	04/16/2014
8	NDC:0113-0604- 02	550 in 1 BOTTLE; Type 0: Not a Combination Product	06/20/2013	06/30/2020
9	NDC:0113-0604- 82	2 in 1 CARTON	03/02/2011	
9		100 in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:0113-0604- 85	250 in 1 BOTTLE; Type 0: Not a Combination Product	12/12/2020	03/29/2023

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA072096	09/15/1989	

Labeler - L. Perrigo Company (006013346)

Revised: 5/2023 L. Perrigo Company