

FLEX-PRIN- ibuprofen tablet

Provision Medical Products

Uses: temporarily relieves minor aches and pains due to: • headache • minor pain of arthritis • the common cold • toothache • backache • menstrual cramps • muscular aches • temporarily reduces fever

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 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.

Warnings:

Allergy Alert: Ibuprofen may cause a severe allergic reaction which may include:

- hives • shock • facial swelling • asthma (wheezing)

Alcohol Warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take Ibuprofen or other pain relievers/ fever reducers.

Ibuprofen may cause stomach bleeding.

Do not use:

- if you have ever had an allergic reaction to any other pain reliever/fever reducer

Ask a doctor before use if you have:

- stomach pain
- problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are:

- under a doctor's care for any serious condition
- taking any other drug

- taking any other product that contains Ibuprofen, or any other pain reliever/fever reducer

When using this product give with food or milk if stomach upset occurs.

Stop use and ask a doctor if:

- an allergic reaction occurs. Seek medical help right away
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- stomach pain or upset gets worse or lasts
- any new symptoms appear
- redness or swelling is present in the painful area

Directions:

- Do not take more than directed.

Adults and children 12 years and older

- Take 1 tablet every 4 to 6 hours while symptoms
- If pain or fever does not respond to 1 tablet, 2 tablets may be used.

Do not exceed 6 tablets in 24 hours, unless as directed by a doctor.

- The smallest effective dose should be used.

Children under 12 year

- Ask a doctor.

Inactive Ingredients:

carnauba wax, croscarmellose sodium, hydroxypropyl methylcellulose, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, silicon dioxide, sodium starch glycolate, stearic acid and titanium dioxide.

ACTIVE INGREDIENT-IBUPROFEN 200 MG

PAIN RELIEVER/FEVER REDUCER



FLEX-PRIN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69103-2525
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
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CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	IBU200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69103-2525-5	250 in 1 CARTON	04/05/2015	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:69103-2525-6	100 in 1 CARTON	04/05/2015	
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
ANDA	ANDA079129	03/31/2015	

Labeler - Provision Medical Products (036936831)

Registrant - Provision Medical Products (036936831)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Limited		860316511	manufacture(69103-2525)