PROBUFEN- ibuprofen tablet
SAMSUNG PHARM IND. CO., LTD.

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.

ACTIVE INGREDIENT

ACTIVE INGREDIENT: Ibuprophen 400mg

INACTIVE INGREDIENT

Inactive ingredients:
lactose, microcrystalline cellulose, magnesium stearate, Light Anhydrous Silicic Acid, titanium oxide, Talc, tar colorant, Hypromellose2910, Polyethylene Glycol, Ethanol, Methylene Chloride

PURPOSE

PURPOSE: Pain reliever, Fever Reducer

DOSAGE AND ADMINISTRATION

Direction
1. Rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, soft tissue injury, non-articular rheumatism, acute gout, psoriatic arthritis:
200-600mg per dosage orally, 3~4 times a day as ibuprofen for adults.
Maximum dosage is 3200mg per day.
2. Juvenile rheumatoid arthiritis:
30-40mg per kg of body weight divided into 3~4 portions per day orally.
3. Mild and moderate pain, common cold:
200-400mg per dosage orally, 3~4 times a day for adults.
Appropriately increase or reduce dosage by age or symptom.
4. Children should take the unit-dose below, 3~4 times a day orally.
The dosage of children weighing less than 30kg should not exceed 500mg per day.
It is advisable to avoid administering on an empty stomach.
Unit-dose for children:
11 - 14 yrs : 200 - 250 mg
7 - 10 yrs : 150 - 200 mg
3 - 6 yrs : 100 - 150 mg
1 - 2 yrs : 50 - 100 mg

INDICATIONS AND USAGE

Uses
1. Major effects
Fever and pain due to rheumatoid arthritis, juvenile rheumatoid arthritis, osteoarthritis (degenerative joint disease), common cold, back pain, dysmenorrhea, and post-operative pain.
2. This can be used also for the following diseases.
Ankylosing spondilytis, headache, toothache, myalgia, neuragia, acute gout, psoriatic arthritis, soft tissue injury (sprain, contusion), non-articular rheumatism (tendinitis, tendosynovitis, synovitis)

WARNINGS

WARNING
1. When those who drink alcohol over three glasses every day regularly with to take this drug or other antipyretic and analgesic, they must consult a doctor or pharmacist. Gastrointestinal bleeding may occur when these people take this drug.
2. Cardiovascular risks: Administering non-steroidal anti-inflammatory drugs (NSAIDs) including this product may lead to severe cardiovascular thrombotic response, myocardial infaction, and stroke. The possibility of abnormal cardiovascular reaction increases in patients with a period. Adverse reactions should be carefully monitored while an adverse reaction occurs.
3. Gastrointestinal risk: Administering NSAIDs including this product may cause severe gastrointestinal adverse reactions that may develop without any warning signs during the administration period. The risk of these adverse reactions increases in old age (elderly people) or in patients who have taken this drug for a long period.

KEEP OUT OF REACH OF CHILDREN

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STORAGE AND HANDLING SECTION

Other informations:
Store in a hemetic container.
Store between 1C to 30C

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL

PROBUFEN

ibuprofen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49789-050
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	400 mg in 537 mg

Inactive Ingredients	
Ingredient Name	**Strength**
lactose (UNII: J2B2A4N98G)	
magnesium stearate (UNII: 70097M6I30)	
Talc (UNII: 7SEV7J4R1U)	
Methylene Chloride (UNII: 588X2YUY0A)	

Product Characteristics			
Color	orange	**Score**	no score
Shape	OVAL	**Size**	15mm
Flavor		**Imprint Code**	SSP4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49789-050-01	537 mg in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/01/2011	

Labeler - SAMSUNG PHARM IND. CO., LTD. (687744425)

Registrant - SAMSUNG PHARM IND. CO., LTD. (687744425)

Establishment

Name	Address	ID/FEI	Business Operations
SAMSUNG PHARM IND. CO., LTD.		687744425	manufacture(49789-050)

Revised: 9/2012 SAMSUNG PHARM IND. CO., LTD.