GOOD SENSE IBUPROFEN- ibuprofen tablet, chewable Dispensing Solutions, Inc.

Perrigo Junior Strength Ibuprofen Tablets, 100 mg Drug Facts

Active ingredient (in each tablet)

Ibuprofen 100 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

temporarily:

- reduces fever
- relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches

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 your child:

- has had stomach ulcers or bleeding problems
- takes a blood thinning (anticoagulant) or steroid drug
- takes other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- takes more or for a longer time than directed

Sore throat warning: Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by doctor.

Do not use

- if the child has 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 your child
- child has a history of stomach problems, such as heartburn
- child has problems or serious side effects from taking pain relievers or fever reducers
- child has not been drinking fluids
- child has lost a lot of fluid due to vomiting or diarrhea
- child has high blood pressure, heart disease, liver cirrhosis, or kidney disease
- child has asthma
- child is taking a diuretic

Ask a doctor or pharmacist before use if the child is

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

When using this product

- mouth or throat burning may occur; give with food or water
- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

- child experiences any of the following signs of stomach bleeding:
- feels faint
- vomits blood
- has bloody or black stools
- has stomach pain that does not get better
- the child does not get any relief within the first day (24 hours) of treatment
- fever or pain gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

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

- this product does not contain directions or complete warnings for adult use
- do not give more than directed
- find the right dose on chart below. If possible, use weight to dose; otherwise use age.
- if needed, repeat dose every 6-8 hours
- do not use more than 4 times a day

Dosing Chart				
Weight (lb)	Age (yr)	Tablets		
under 24	under 2	ask a doctor		
24-35	2-3	1		
36-47	4-5	1 ½		
48-59	6-8	2		
60-71	9-10	2 ½		
72-95	11	3		

Other information

- phenylketonurics: contains phenylalanine 6 mg per tablet
- do not use if printed seal under cap is broken or missing
- store at 20-25°C (68-77°F)
- see end panel for lot number and expiration date

Inactive ingredients

acesulfame potassium, ammonium glycerrhizin, aspartame, carnauba wax, croscarmellose sodium, FD&C yellow no. 6 aluminum lake, hypromellose, magnesium stearate, mannitol, natural and artificial flavors, prosweet, silicon dioxide, sodium lauryl sulfate, soybean oil, succinic acid

Questions or comments?

1-800-719-9260

Principal Display Panel

For Ages 2 to 11

See New Warnings Information

Junior Strength Ibuprofen Tablets, 100 mg

Lasts Up To 8 Hours

Pain Reliever / Fever Reducer (NSAID)

Orange Flavor

Compare to active ingredient of Motrin® Junior Strength

NDC 68258-2994-02



GOOD SENSE IBUPROFEN

ibuprofen tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68258-2994(NDC:0113-0461)
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
IBUPRO FEN (UNII: WK2XYI10 QM) (IBUPRO FEN - UNII: WK2XYI10 QM)	IBUPROFEN	100 mg	

Inactive Ingredients				
Ingredient Name	Strength			
ASPARTAME (UNII: Z0H242BBR1)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MANNITOL (UNII: 3OWL53L36A)				
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)				
SO DIUM LAURYL SULFATE (UNII: 368GB5141J)				
SO YBEAN OIL (UNII: 241ATL177A)				
SUCCINIC ACID (UNII: AB6MNQ6J6L)				
ACESULFAME POTASSIUM (UNII: 230 V73Q5G9)				

Product Characteristics				
Color	ORANGE	Score	2 pieces	
Shape	ROUND	Size	13mm	
Flavor	ORANGE	Imprint Code	L461	
Contains				

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68258-2994-2	24 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076359	11/09/2004	

Labeler - Dispensing Solutions, Inc. (066070785)

Registrant - PSS World Medical, Inc. (101822682)

Establishment

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	relabel(68258-2994), repack(68258-2994)

Revised: 11/2013 Dispensing Solutions, Inc.