

NDA 20812

APPROVED

JAN 12 2000

Principal Display Panel – Carton

New Infant Dosing Fruit Flavor
For Ages 6 mos - 23 mos
Infants' Advil Concentrated Drops
IBUPROFEN ORAL SUSPENSION
50 mg per 1.25 mL
Fever Reducer/Pain Reliever
Lasts up to 8 Hours
FRUIT-FLAVORED
DROPS
Alcohol-Free
½ FL OZ (15 mL) and 1/4 FL OZ (7.5 mL)

Back Panel

Important: Read all product information before using. Keep this box for important information. This product is intended for use in children ages 6 months-23 months.

Drug Facts

<i>Active ingredient (in each 1.25mL)</i>	<i>Purposes</i>
Ibuprofen 50 mg.....	Fever reducer/pain reliever

Uses temporarily:

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

Allergy alert: ibuprofen may cause a severe allergic reaction which may include:

- hives
 - facial swelling
 - asthma (wheezing)
 - shock
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Do not use if the child has ever had an allergic reaction to any other fever reducer/pain reliever

Ask a doctor before use if the child has

- not been drinking fluids
 - lost a lot of fluid due to continued vomiting or diarrhea
 - stomach pain
 - problems or serious side effects from taking fever reducers or pain relievers
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Ask a doctor or pharmacist before use if the child is

- 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
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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.

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- fever or pain gets worse or lasts more than 3 days
- the child does not get any relief within first day (24 hours) of treatment
- stomach pain or upset gets worse or lasts
- 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.

Directions

- do not give more than directed
- shake well before using
- find right dose on chart below. If possible, use weight to dose; otherwise use age.
- measure with the dosing device provided. Do not use with any other device.
- repeat dose every 6-8 hours, if needed
- do not use more than 4 times a day

Dosing Chart

Weight (lb)	Age (mos)	Dose (mL)
under 6 mos		ask a doctor
12-17 lb	6-11 mos	1.25 mL
18-23 lb	12-23 mos	1.875 mL

See other side panel for more information →

Other information • one dose lasts 6 – 8- hours • store at 20 – 25 °C (68 – 77°F)
• see bottom of box for lot number and expiration date

Inactive ingredients artificial flavors, carboxymethylcellulose sodium, citric acid, edetate disodium, FD&C Red No. 40, FD&C Blue No. 1, glycerin, microcrystalline cellulose, polysorbate 80, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum

Questions or Comments?

- call toll-free 1-800-88-ADVIL

Or ask your pharmacist, doctor or health care professional

Whitehall-Robins Healthcare
Madison, NJ 07940
Made in USA

Barcode

This label may not be the latest approved by FDA.
For current labeling information, please visit <https://www.fda.gov/drugsatfda>

