

**CHILDRENS FLANAX ORAL- ibuprofen suspension**  
**Belmora LLC**

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**FLANAX IBUPROFEN ORAL SUSPENSION**

***Drug Facts***

***Active ingredient (in each 5 mL)***

Ibuprofen USP 100 mg (NSAID)\*  
\*nonsteroidal anti-inflammatory drug

***Purpose***

Pain reliever/ fever reducer

***Uses***

temporarily:

- relieves minor aches and pains due to the common cold, flu, sore throat, headache and toothache
- 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 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

**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.

**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 ibuprofen or 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, kidney disease, or had a stroke
- 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**

- take with food or milk if stomach upset occurs

**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
- child has symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - weakness in one part or side of body
  - slurred speech
  - leg swelling
- the child does not get any relief within 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**
- shake well before using
- mL = milliliter
- find right dose on chart. If possible, use weight to dose; otherwise use age.
- use only enclosed dosing cup. Do not use any other dosing device.
- if needed, repeat dose every **6 to 8 hours**
- do not use more than **4 times a day**

- replace original bottle cap to maintain child resistance
- wash dosage cup after each use

### Dosing Chart

Weight (lb)	Age (year)	Dose (mL)*
under 24 lbs	under 2 years	ask a doctor
24-35 lbs	2-3 years	5 mL
36-47 lbs	4-5 years	7.5 mL
48-59 lbs	6-8 years	10 mL
60-71 lbs	9-10 years	12.5 mL
72-95 lbs	11 years	15 mL

\* or as directed by a doctor

### Other information

• **each 5 mL contains:** sodium 2 mg • store between 20 to 25°C (68 to 77°F) • **do not use if carton is opened or seal under cap opening is broken or missing** • see bottom panel for lot number and expiration date

### Inactive ingredients

Acesulfame potassium, citric acid anhydrous, D&C yellow No. 10, FD&C red No. 40, glycerin, hypromellose, N&A flavor for cherry blast, N&A strawberry flavor wild, polysorbate 80, pregelatinized starch (potato), propylene glycol, purified water, sodium benzoate, sucrose and xanthan gum

### Questions or comments?

**1-888-779-2877**

9AM-5PM EST Mon-Fri.

### LASTS UP TO 8 HOURS

for kids

**Berry Flavor**

**Alcohol Free**

**Important: Read all product information before using.**

**Keep this box for important information.**

**This product is intended for use in children.**

**KEEP IN OUTER CARTON UNTIL CONTENTS USED**

Distributed by: **Belmora LLC,**

3033 Wilson Blvd., Suite 700, Arlington, VA 22201

Made in India

Packaging

**FLANAX**  
for kids  
para niños

**Drug Facts**

**Propósito**  
Ibuprofeno USP 100 mg (NSAID)\*.....Pain reliever/fever reducer

**Usos**  
temporarily:  
relieves minor aches and pains due to the common cold, flu, sore throat, headache and toothache  
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

KEEP IN OUTER CARTON UNTIL CONTENTS USED

**Drug Facts (continued)**

**Dosing Chart / Tabla de Dosificación**

Weight (lb) / Peso (lb)	Age (year) / Edad (años)	Dose (mL)* / Dosis (mL)*
under 24 / menores de 24 lbs	under 2 years / menores de 2 años	ask a doctor / consulte a un médico
24-35 lbs	2-3 years/años	5 mL
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72-95 lbs	11 years/años	15 mL

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**Other information**  
each 5 mL contains: sodium 2 mg ■ store between 20 to 25°C (68 to 77°F) ■ do not use if carton is opened or seal under cap opening is broken or missing ■ see bottom panel for lot number and expiration date

**Instructions**  
this product does not contain instructions or warnings for use in children  
do not administer to children  
do not use if the child has had a stomach ulcer or bleeding problem  
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**Inactive ingredients**  
Acetylsalicylic acid, citric acid anhydrous, D&C yellow No. 10, FD&C red No. 40, glycerin, hypromellose, NSA flavor for cherry blast, NSA strawberry flavor wild, polyethylene glycol, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sucrose and xanthan gum

**Questions or comments?** 1-888-776-2877 9AM-5PM EST Mon-Fri

Para obtener más información sobre el producto, consulte el interior de la caja.  
Distribuido por: Balmora LLC, 3083 Wilson Blvd., Suite 700, Arlington, VA 22201  
Made in India. Fabricado en India.  
Code: AP DRUGS/04/2016

NDC 27864-777-99

**FLANAX**  
100mg/5ml SUSPENSION ORAL DE  
IBUPROFENO (AINE) / 100mg/5ml  
IBUPROFEN ORAL SUSPENSION (NSAID)

**ANALGÉSICO/ANTIPIRÉTICO  
DURA HASTA 8 HORAS /  
PAIN RELIEVER FEVER REDUCER  
LASTS UP TO 8 HOURS**

**for kids**  
para niños

- Berry Flavor Sabor de Bayas
- Alcohol Free Sin alcohol

FL OZ (120 mL)

**Important: Read all product information before using.**  
Keep this box for important information.  
This product is intended for use in children.

**Drug Facts**

**Active ingredient (in each 5 mL):** Ibuprofen USP 100 mg (NSAID)\*.....Pain reliever/fever reducer

**Purpose:** nonsteroidal anti-inflammatory drug

**Uses**  
temporarily:  
relieves minor aches and pains due to the common cold, flu, sore throat, headache and toothache  
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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  
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. Some throat warning: Sore 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 ibuprofen or 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

**Drug Facts (continued)**

child has lost a lot of fluid due to vomiting or diarrhea  
child has high blood pressure, heart disease, liver cirrhosis, kidney disease, or had a stroke  
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**  
take with food or milk if stomach upset occurs

**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  
child has symptoms of heart problems or stroke:

8 53030 00288 5

P1052899 LM-5402

Lot: EXP:

DRUG FACTS LABEL

**Drug Facts**

**Active ingredient (in each 5 mL):** Ibuprofen USP 100 mg (NSAID)\*.....Pain reliever/fever reducer

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expiration date

**Inactive ingredients**

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**Questions or comments? ☎ 1-888-779-2877**  
9AM-5PM EST Mon-Fri.

# CHILDRENS FLANAX ORAL

ibuprofen suspension

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:27854-777
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	100 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 230V73Q5G9)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYPROMELLOSE 2208 (4000 MPA.S)</b> (UNII: 39J80LT57T)	
<b>CHERRY</b> (UNII: BUC5I9595W)	
<b>STRAWBERRY</b> (UNII: 4J2TY8Y81V)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>STARCH, POTATO</b> (UNII: 8I089SAH3T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27854-777-99	1 in 1 CARTON	01/26/2024	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209179	01/26/2024	

**Labeler** - Belmora LLC (112753244)

Revised: 1/2024

Belmora LLC