

**INFANTS ADVIL- ibuprofen suspension/ drops**  
**Wyeth Consumer Healthcare LLC**

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**INFANT'S ADVIL CONCENTRATED DROPS**  
**INFANT'S ADVIL CONCENTRATED DROPS (Dye-Free)**  
**(Ibuprofen)**

***Drug Facts***

***Active ingredient (in each 1.25 mL)***

Ibuprofen 50 mg (NSAID)<sup>1</sup>

<sup>1</sup> nonsteroidal anti-inflammatory drug

***Purpose***

Fever reducer/Pain reliever

***Uses***

temporarily:

- reduces fever
- relieves minor aches and pains due to the common cold, flu, 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 the 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.

**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 the child
- child has problems or serious side effects from taking pain relievers or fever reducers
- child has a history of stomach problems, such as heartburn
- child has high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- child has not been drinking fluids
- child has lost a lot of fluid due to vomiting or diarrhea
- 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 the body
  - slurred speech
  - leg swelling
- 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.

**Directions**

- **this product does not contain directions or complete warnings for adult use**
- **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.
- repeat dose every **6-8 hours**, if needed
- do not use more than **4 times a day**
- measure with the dosing device provided. Do not use with any other device.

### 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

#### **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**

acetic acid, artificial flavor, butylated hydroxytoluene, carboxymethylcellulose sodium, citric acid monohydrate, edetate disodium, glycerin, microcrystalline cellulose, polysorbate 80, propylene glycol, 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  
For most recent product information, visit [www.Advil.com](http://www.Advil.com).

#### **PRINCIPAL DISPLAY PANEL - 15 mL Bottle Label**

**Infants'**

**Advil®**

**Concentrated Drops**

**Ibuprofen Oral Suspension**

**50 mg per 1.25 mL**

**Pain Reliever/Fever Reducer (NSAID)**

**White Grape-Flavored Drops**

1/2 FL OZ (15 mL)

**Infants'**  
**Advil®**  
Concentrated Drops  
Ibuprofen Oral Suspension  
50 mg per 1.25 mL  
Pain Reliever/Fever Reducer (NSAID)

White Grape-Flavored Drops  
1/2 FL OZ (15 mL)

**READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION**

*Active ingredient* Ibuprofen 50 mg in each 1.25 mL  
*Uses* temporarily reduces fever, relieves minor aches and pains due to the common cold, flu, headaches and toothaches

**SHAKE WELL**

**Do Not Use** if plastic wrap imprinted with "SAFETY SEAL" is broken or missing.

*Warnings*  
**Ask doctor before use** if child is under a doctor's care for a serious condition, taking other drugs or has stomach problems.

LIFT HERE



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 allergic reaction occurs, stop use, seek medical help right away. **Do not use** if child has ever had an allergic reaction to any pain reliever/fever reducer. **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if the 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.

*Directions* Does not contain directions or complete warnings for adult use. **Do not give more than directed. Shake well before using.** Find right dose on chart. Use weight to dose; otherwise use age. Repeat dose every **6-8 hours**, if needed. Do not use more than **4 times a day**. Measure with the dosing device provided.

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

Pfizer, Madison, NJ 07940 USA  
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PAA082316

Questions or comments? call 1-800-88-Advil

**PRINCIPAL DISPLAY PANEL - 15 mL Bottle Carton**

**Infants'**  
**Advil®**  
**Concentrated Drops**  
**Ibuprofen Oral Suspension**  
**50 mg per 1.25 mL**  
**Pain Reliever/Fever Reducer (NSAID)**  
**Fever**  
**Aches & Pains**  
**Lasts Up To**  
**8**  
**Hours**

Dye-Free

White Grape Flavored Drops  
for ages 6–23 months

1/2 FL OZ (15 mL)

Alcohol-Free



PRINCIPAL DISPLAY PANEL - 30 mL Bottle Label

Infants'  
Advil®  
Concentrated Drops

Ibuprofen Oral Suspension  
50 mg per 1.25 mL  
Pain Reliever/Fever Reducer (NSAID)

White Grape-Flavored Drops

1 FL OZ (30 mL)

Infants'  
**Advil**<sup>®</sup>  
Concentrated Drops  
Ibuprofen Oral Suspension  
50 mg per 1.25 mL  
Pain Reliever/Fever Reducer (NSAID)

White Grape- Flavored Drops  
1 FL OZ (30 mL)

**READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION**

*Active ingredient* Ibuprofen  
50 mg in each 1.25 mL

*Uses* temporarily reduces fever, relieves minor aches and pains due to the common cold, flu, headaches and toothaches

**SHAKE WELL**

Do Not Use if plastic wrap imprinted with "SAFETY SEAL" is broken or missing.

*Warnings*  
**Ask doctor before use** if child is under a doctor's care for a serious condition, taking other drugs or has stomach problems.

LIFT HERE

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 allergic reaction occurs, stop use, seek medical help right away. **Do not use** if child has ever had an allergic reaction to any pain reliever/fever reducer. **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if the 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.

**Directions** Does not contain directions or complete warnings for adult use. Do not give more than directed. Shake well before using. Find right dose on chart. Use weight to dose; otherwise use age. Repeat dose every 6-8 hours, if needed. Do not use more than 4 times a day. Measure with the dosing device provided.

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

**Questions or comments?**  
call **1-800-88-Advil**  
Pfizer, Madison, NJ 07940 USA  
For most recent product information, visit [www.Advil.com](http://www.Advil.com).  
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**PRINCIPAL DISPLAY PANEL - 30 mL Bottle Carton**

**VALUE Size**

**Infants'  
Advil<sup>®</sup>**

**Concentrated Drops**

**Ibuprofen Oral Suspension**

**50 mg per 1.25 mL**

**Pain Reliever/Fever Reducer (NSAID)**

**Fever**

**Aches & Pains**



**Ibuprofen Oral Suspension**  
**50 mg per 1.25 mL**  
**Pain Reliever/Fever Reducer (NSAID)**  
**White Grape-Flavored Drops**  
 3/4 FL OZ (22.5 mL)

<p><b>Infants'</b>  <b>Advil®</b>          Concentrated Drops          Ibuprofen Oral Suspension          50 mg per 1.25 mL  <b>Pain Reliever/Fever Reducer (NSAID)</b></p> <p>White Grape-Flavored Drops          3/4 FL OZ (22.5 mL)</p>	<p><b>READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION</b></p>	<p><b>SHAKE WELL</b></p> <p>Do Not Use if plastic wrap imprinted with "SAFETY SEAL" is broken or missing.</p>
	<p><b>Active ingredient</b> Ibuprofen          50 mg in each 1.25 mL  <b>Uses</b> temporarily reduces fever, relieves minor aches and pains due to the common cold, flu, headaches and toothaches</p>	<p><b>Warnings</b>          Ask doctor before use if child is under a doctor's care for a serious condition, taking other drugs or has stomach problems. ➔</p> <p><b>LIFT HERE</b></p>

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 allergic reaction occurs, stop use, seek medical help right away. **Do not use** if child has ever had an allergic reaction to any pain reliever/fever reducer. **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if the 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. ➔

**Directions** Does not contain directions or complete warnings for adult use. Do not give more than directed. Shake well before using. Find right dose on chart. Use weight to dose; otherwise use age. Repeat dose every 6-8 hours, if needed. Do not use more than 4 times a day. Measure with the dosing device provided.

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

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 For most recent product information, visit [www.Advil.com](http://www.Advil.com).  
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Questions or comments? call 1-800-88-Advil

PAA082445

**PRINCIPAL DISPLAY PANEL - 22.5 mL Bottle Carton**

**50% MORE FREE**

**Infants'**  
**Advil®**  
**Concentrated Drops**

**Ibuprofen Oral Suspension**  
**50 mg per 1.25 mL**  
**Pain Reliever/Fever Reducer (NSAID)**

**Fever**

**Aches & Pains**

**Lasts Up To**

**8**

**Hours**

**Dye-Free**

Alcohol-Free

**White Grape Flavored Drops**  
**for ages 6–23 months**

1/2 FL OZ +

**1/4 FL OZ**

**FREE**

= 3/4 FL OZ (22.5 mL)

# Infants' Advil<sup>®</sup>

Concentrated Drops

Do Not Use if plastic wrap imprinted with  
"SAFETY SEAL" is broken or missing.

Child-Resistant Safety Cap

**50% MORE FREE**

# Infants' Advil<sup>®</sup>

Concentrated Drops  
Ibuprofen Oral Suspension  
50 mg per 1.25 mL  
Pain Reliever/Fever Reducer (NSAID)

**Fever**

Aches & Pains

Lasts Up To

**8**  
Hours



**Dye-Free**

Alcohol-Free

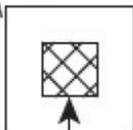
White Grape Flavored Drops  
for ages **6-23** months

1/2 FL OZ + **1/4 FL OZ FREE** = 3/4 FL OZ (22.5 mL)

For most recent product information, visit [www.Advil.com](http://www.Advil.com).

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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

#### Active ingredient Purpose (in each 1.25 mL)

Ibuprofen 50 mg Fever reducer/  
(NSAID)\* ..... Pain reliever  
\*nonsteroidal anti-inflammatory drug

#### Uses temporarily:

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



## UNVARNISHED AREA

UNVARNISHED AREA

### Drug Facts (continued)

**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.

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

### Directions

- this product does not contain directions or complete warnings for adult use
- do not give more than directed
- shake well before using
- find right dose on chart. If possible, use weight to dose; otherwise use age.

### Drug Facts (continued)

- repeat dose every 6-8 hours, if needed
- do not use more than 4 times a day
- measure with the dosing device provided. Do not use with any other device.

#### 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

### 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

acetic acid, artificial flavor, butylated hydroxytoluene, carboxymethylcellulose sodium, citric acid monohydrate, edetate disodium, glycerin, microcrystalline cellulose, polysorbate 80, propylene glycol, 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

Rinse the oral syringe with tap water only.



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PAA082444

UNVARNISHED AREA

## INFANTS ADVIL

ibuprofen suspension/ drops

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0573-0191
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	50 mg in 1.25 mL

### Inactive Ingredients

Ingredient Name	Strength
ACETIC ACID (UNII: Q40Q9N063P)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	WHITE (Translucent off-white)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE (White grape)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:0573-0191			

1	NDC:0573-0191-20	1 in 1 CARTON	01/30/1998	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:0573-0191-50	1 in 1 CARTON	01/30/1998	
2		30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
3	NDC:0573-0191-22	1 in 1 CARTON	01/30/2014	
3		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
4	NDC:0573-0191-75	1 in 1 CARTON	01/30/1998	
4		22.5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020812	01/30/1998	

**Labeler** - Wyeth Consumer Healthcare LLC (828831730)

**Registrant** - Pfizer Inc (113480771)

### Establishment

Name	Address	ID/FEI	Business Operations
PF Consumer Healthcare Canada ULC		203812479	ANALYSIS(0573-0191) , LABEL(0573-0191) , MANUFACTURE(0573-0191) , PACK(0573-0191)

Revised: 6/2019

Wyeth Consumer Healthcare LLC