CHILDRENS ADVIL- ibuprofen suspension
Haleon US Holdings LLC

Drug Facts

ACTIVE INGREDIENT (IN EACH 5 ML)

Ibuprofen 100 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

PURPOSE

Fever reducer/Pain reliever

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 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.

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 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, or 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

- 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.

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 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 only with the dosing cup provided. Dosing cup to be used with Children's Advil Suspension only. Do not use with other products. Dose lines account for product remaining in cup due to thickness of suspension.

Dosing Chart

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

OTHER INFORMATION

Children's Advil Suspension Fruit Flavor; Children's Advil Suspension Grape Flavor; Children's Advil Suspension White Grape Flavor; Children's Advil Bubblegum

- each 5 mL contains: **sodium 3 mg**
- one dose lasts 6-8 hours
- store at 20-25°C (68-77°F)
- see bottom of box for lot number and expiration date

Children's Advil Suspension Blue Raspberry Flavor; Children's Advil Suspension Sugar-Free Dye-Free Berry Flavor

- each 5 mL contains: **sodium 10 mg**
- 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

Children's Advil Suspension Fruit Flavor

artificial flavor, carboxymethylcellulose sodium, citric acid monohydrate, edetate disodium, FD&C red no. 40, glycerin, microcrystalline cellulose, polysorbate 80, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum

Children's Advil Suspension Grape Flavor

acetic acid, artificial flavor, butylated hydroxytoluene, carboxymethylcellulose sodium, citric acid monohydrate, edetate disodium, FD&C blue no.1, FD&C red no. 40, glycerin, microcrystalline cellulose, polysorbate 80, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum

Children's Advil Suspension Blue Raspberry Flavor

artificial and natural flavors, carboxymethylcellulose sodium, citric acid monohydrate, edetate disodium, FD&C blue no. 1, glycerin, microcrystalline cellulose, polysorbate 80, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucrose, xanthan gum

Children's Advil Suspension White Grape Flavor

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

Children's Advil Suspension Bubblegum Flavor

carboxymethylcellulose sodium, citric acid monohydrate, edetate disodium, FD&C red no. 40, glycerin, microcrystalline cellulose, natural and artificial flavor, polysorbate 80, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum

Children's Advil Suspension Sugar-Free Dye-Free Berry

artificial flavor, +orbate 80, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, xanthan gum

QUESTIONS OR COMMENTS?

call toll-free **1-800-88-ADVIL** or ask your pharmacist, doctor or health care professional

PRINCIPAL DISPLAY PANEL

NDC 0573-0174-30

Children's
Advil®
Suspension

Ibuprofen Oral Suspension
100 mg per 5 mL
Pain Reliever/Fever Reducer (NSAID)

Fever

Aches & Pains
Lasts Up To
8
Hours

BLUE
RASPBERRY!

Blue Raspberry-Flavored Liquid
for ages 2-11 years

4 FL OZ (120 mL)
Alcohol-Free

PRINCIPAL DISPLAY PANEL

NDC 0573-0171-30

Children's
Advil®
Suspension

Ibuprofen Oral Suspension
100 mg per 5 mL
Pain Reliever/Fever Reducer (NSAID)

Fever

Aches & Pains
Lasts Up To
8
Hours

Grape-Flavored Liquid
for ages 2-11 years

4 FL OZ (120 mL)
Alcohol-Free

PRINCIPAL DISPLAY PANEL

NDC 0573-0170-30

Children's
Advil®
Suspension

Ibuprofen Oral Suspension
100 mg per 5 mL
Pain Reliever/Fever Reducer (NSAID)

Fever

Aches & Pains

Lasts Up To
8
Hours

Fruit-Flavored Liquid
for ages
2-11 years

4 FL OZ (120 mL)
Alcohol-Free

PRINCIPAL DISPLAY PANEL

NDC0573-0290-30

Children's
Advil®
Suspension

Ibuprofen Oral Suspension
100 mg per 5 mL
Pain Reliever/Fever Reducer (NSAID)

Fever

Aches & Pains
Lasts Up To
8
Hours

Dye-Free
WHITE GRAPE

White Grape-Flavored Liquid
for ages 2-11 years

4 FL OZ (120 mL)
Alcohol-Free

PRINCIPAL DISPLAY PANEL

NDC 0573-0207-30

Children's
Advil®
Suspension

Ibuprofen Oral Suspension
100 mg per 5 mL
Pain Reliever/Fever Reducer (NSAID)

Fever

Aches & Pains
Lasts Up To
8
Hours

Bubble Gum

Bubble Gum-Flavored Liquid for ages 2-11 years

4 FL OZ (120 mL)
Alcohol-Free

PRINCIPAL DISPLAY PANEL

NDC 0573-0232-30

SUGAR-FREE

Children's Advil®
Suspension

Ibuprofen Oral Suspension
100 mg per 5 mL
Pain Reliever/Fever Reducer (NSAID)

Fever

Aches & Pains
Lasts Up To
8
Hours

Dye-Free
BERRY

Berry-Flavored Liquid
for ages 2-11 years

4 FL OZ (120 mL)
Alcohol-Free

CHILDRENS ADVIL

ibuprofen suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0573-0174
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	BLUE (Translucent, medium dark blue)	**Score**	
Shape		**Size**	
Flavor	RASPBERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0174-30	1 in 1 CARTON	06/27/1996	07/31/2022
1		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020589	06/27/1996	

CHILDRENS ADVIL

ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0573-0171
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ACETIC ACID (UNII: Q40Q9N063P)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	PURPLE (Translucent purple)	**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0171-30	1 in 1 CARTON	06/27/1996	
1		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:0573-0171-03	1 in 1 CARTON	06/27/1996	
2		30 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
3	NDC:0573-0171-32	2 in 1 PACKAGE	06/27/1996	
3		1 in 1 CARTON		
3		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020589	06/27/1996	

CHILDRENS ADVIL

ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0573-0170
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	RED (Translucent red)	**Score**	
Shape		**Size**	
Flavor	FRUIT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0170-30	1 in 1 CARTON	06/27/1996	
1		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
	NDC:0573			

2	NDC:0573-0170-01	1 in 1 CARTON	06/27/1996	
2		30 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
3	NDC:0573-0170-32	1 in 1 CARTON	06/27/1996	
3		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020589	06/27/1996	

CHILDRENS ADVIL

ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0573-0290
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ACETIC ACID (UNII: Q40Q9N063P)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (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

Color		**Score**	

Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0290-30	1 in 1 CARTON	12/01/2010	
1		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:0573-0290-01	1 in 1 CARTON	12/01/2010	
2		30 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020589	12/01/2010	

CHILDRENS ADVIL

ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0573-0207
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
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			
Color	PINK	**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0207-30	1 in 1 CARTON	09/04/2012	
1		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020589	09/04/2012	

CHILDRENS ADVIL

ibuprofen suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0573-0232
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (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)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0232-30	1 in 1 CARTON	12/20/2013	
1		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020589	12/20/2013	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 2/2024 Haleon US Holdings LLC