

CHILDRENS IBUPROFEN BUBBLEGUM - ibuprofen suspension/ drops
CHILDRENS IBUPROFEN GRAPE - ibuprofen suspension/ drops
CHILDRENS IBUPROFEN BLUE RASPBERRY - ibuprofen suspension/ drops
CHILDRENS IBUPROFEN FRUIT - ibuprofen suspension/ drops
Guardian Drug Company

Guardian Children's Ibuprofen Oral Suspension

ACTIVE INGREDIENT (in each 5 mL)

Ibuprofen, USP 100 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

PURPOSE

Pain reliever/fever reducer

USE(S)

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
- asthma (wheezing)
- skin reddening
- facial swelling
- shock
- 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 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
- 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 **6-8 hours**
- do not use more than **4 times a day**
- replace original bottle cap to maintain child resistance

Dosing Chart

Weight (lb)	Age (yr)	Dose (mL)*
under 24	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 20-25°C (68-77°F)
- **do not use if carton is opened or if printed inner seal imprinted with "SEALED for YOUR PROTECTION" is broken or missing.**

INACTIVE INGREDIENTS

bubblegum flavor: anhydrous citric acid, FD&C red no. 40, flavor, glycerin, polysorbate 80, pregelatinized starch, purified water, sodium benzoate, sucrose, xanthan gum

grape flavor: anhydrous citric acid, D&C red no. 33, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin, polysorbate 80, pregelatinized starch, purified water, sodium benzoate, sucrose, xanthan gum

fruit flavor: anhydrous citric acid, FD&C red no. 40, flavors, glycerin, polysorbate 80, pregelatinized starch, purified water, sodium benzoate, sucrose, xanthan gum

blue raspberry flavor: anhydrous citric acid, FD&C blue no. 1, flavors, glycerin, polysorbate 80, pregelatinized starch, purified water, sodium benzoate, sucrose, xanthan gum

QUESTIONS OR COMMENTS?

call 1-609-860-2600 (Monday - Friday 8 am - 4 pm)

PRINCIPAL DISPLAY PANEL

NDC 53041-572-03

GUARDIAN

For Ages 2 to 11 Years

Children's Ibuprofen

Oral Suspension, USP (NSAID)

100 mg per 5 mL

Pain Reliever/Fever Reducer

- Lasts up to 8 Hours
- No Artificial Sweetener
- Alcohol Free

Bubble Gum Flavor

4 FL OZ (120 mL)



PRINCIPAL DISPLAY PANEL

NDC 53041-639-03

GUARDIAN

For Ages 2 to 11 Years

Children's Ibuprofen

Oral Suspension, USP (NSAID)

- 100 mg per 5 mL
Pain Reliever/Fever Reducer
- Lasts up to 8 Hours
 - No Artificial Sweetener
 - Alcohol Free

Grape Flavor
4 FL OZ (120 mL)

No Coating Area
COATING FREE AREA

COATING FREE AREA

Glue

N.C.

GUARDIAN

For Ages 2 to 11 Years
Children's Ibuprofen

Oral Suspension, USP (NSAID)
100 mg per 5 mL

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

Drug Facts (continued)

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 the 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. →

Drug Facts (continued)

- if needed, repeat dose every 6-8 hours
- do not use more than 4 times a day
- replace original bottle cap to maintain child resistance

Dosing Chart

Weight (lb)	Age (yr)	Dose (mL)*
under 24	under 2 years	ask a doctor
24-35 lbs	2-3 years	5 mL
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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 20-25°C (68-77°F)
- do not use if carton is opened or if printed inner seal imprinted with "SEALED FOR YOUR PROTECTION" is broken or missing.

Inactive ingredients anhydrous citric acid, D&C red no. 33, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin, polysorbate 80, pregelatinized starch, purified water, sodium benzoate, sucrose, xanthan gum.

Questions or comments?
Call 1-609-860-2600 (Monday - Friday 8 am - 4 pm)

Manufactured by:
Guardian Drug Company
2 Charles Court
Dayton, NJ 08810 USA

NDC 53041-639-03

GUARDIAN

For Ages 2 to 11 Years
Children's Ibuprofen

Oral Suspension, USP (NSAID)
100 mg per 5 mL

Pain Reliever/Fever Reducer

- Lasts up to 8 Hours
- No Artificial Sweetener
- Alcohol Free



Grape Flavor

4 FL OZ (120 mL)

MFR# 53041 REV 0620



0 53041 63903 6

LOT:
EXP:

COATING FREE AREA

No Coating Area

PRINCIPAL DISPLAY PANEL

NDC 53041-632-03

GUARDIAN

For Ages 2 to 11 Years

Children's Ibuprofen

Oral Suspension, USP (NSAID)

100 mg per 5 mL

Pain Reliever/Fever Reducer

- Lasts up to 8 Hours
- No Artificial Sweetener
- Alcohol Free

Fruit Flavor

4 FL OZ (120 mL)



PRINCIPAL DISPLAY PANEL

NDC 53041-638-03

GUARDIAN
 For Ages 2 to 11 Years
 Children's Ibuprofen
 Oral Suspension, USP (NSAID)
 100 mg per 5 mL
 Pain Reliever/Fever Reducer

- Lasts up to 8 Hours

- No Artificial Sweetener
- Alcohol Free

Blue Raspberry Flavor
4 FL OZ (120 mL)

No Coating Area
COATING FREE AREA

Drug Facts (continued)

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
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- 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

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- feels faint
- vomits blood
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- has stomach pain that does not get better
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- chest pain
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- weakness in one part or side of the body
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- 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

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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.

Drug Facts (continued)

- if needed, repeat dose every 6-8 hours
- do not use more than 4 times a day
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Dosing Chart

Weight (lb)	Age (yr)	Dose (mL)*
under 24	under 2 years	ask a doctor
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Other information

- each 5 mL contains: sodium 2 mg
- store between 20-25°C (68-77°F)
- do not use if carton is opened or if printed inner seal imprinted with "SEALED for YOUR PROTECTION" is broken or missing.

Inactive ingredients: anhydrous citric acid, FD&C blue no. 1, flavor, glycerin, polysorbate 80, pregelatinized starch, purified water, sodium benzoate, sucrose, xanthan gum.

Questions or comments?
Call 1-809-860-2600 (Monday - Friday 8 am - 4 pm)

Manufactured by:
Guardian Drug Company
2 Charles Court
Dayton, NJ 08810 USA

Drug Facts

Active ingredient (in each 5 mL)	Purpose
ibuprofen, USP 100 mg (NSAID)*	Pain reliever/fever reducer

*nonsteroidal anti-inflammatory drug

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.

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- 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.

COATING FREE AREA

Glue

N.C.

COATING FREE AREA
No Coating Area



GUARDIAN®
For Ages 2 to 11 Years
Children's Ibuprofen
Oral Suspension, USP (NSAID)
100 mg per 5 mL

NDC 53041-638-03

GUARDIAN®

For Ages 2 to 11 Years
Children's Ibuprofen
Oral Suspension, USP (NSAID)
100 mg per 5 mL

Pain Reliever/Fever Reducer

- Lasts up to 8 Hours
- No Artificial Sweetener
- Alcohol Free



Blue Raspberry Flavor

4 FL OZ (120 mL)

MFR# 53041 REV 1120



0 53041 63803 9

LOT:
EXP:

CHILDRENS IBUPROFEN BUBBLEGUM

ibuprofen suspension/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53041-572
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
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:53041-572-03	1 in 1 CARTON	10/13/2021	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:53041-572-04	1 in 1 CARTON	10/13/2021	
2		240 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	ANDA210149	10/13/2021	

CHILDRENS IBUPROFEN GRAPE

ibuprofen suspension/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53041-639
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	PURPLE	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53041-639-03	1 in 1 CARTON	10/13/2021	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:53041-639-04	1 in 1 CARTON	10/13/2021	
2		240 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	ANDA210149	10/13/2021	

CHILDRENS IBUPROFEN BLUE RASPBERRY

ibuprofen suspension/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53041-638
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	BLUE	Score	
Shape		Size	
Flavor	RASPBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53041-638-03	1 in 1 CARTON	10/13/2021	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:53041-638-04	1 in 1 CARTON	10/13/2021	
2		240 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	ANDA210149	10/13/2021	

CHILDRENS IBUPROFEN FRUIT

ibuprofen suspension/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53041-632
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3S)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor	FRUIT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53041-632-03	1 in 1 CARTON	10/13/2021	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		

2	NDC:53041-632-04	1 in 1 CARTON	10/13/2021	
2		240 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	ANDA210149	10/13/2021	

Labeler - Guardian Drug Company (119210276)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(53041-572, 53041-632, 53041-638, 53041-639)

Revised: 10/2021

Guardian Drug Company