

CHILDRENS IBUPROFEN- ibuprofen suspension
Chain Drug Marketing Association, Inc.

Children's Ibuprofen Oral Suspension

Drug Facts

Active ingredient
(in each 5 mL)

Ibuprofen 100 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Ibuprofen 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 **6-8 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	11years	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 printed bottle neckband is broken or missing**
- see bottom panel for lot number and expiration date

Inactive ingredients

Acesulfame potassium, anhydrous citric acid, carboxymethylcellulose sodium, D&C Yellow #10, FD&C Red #40, flavors, glycerin, microcrystalline cellulose, polysorbate 80, propylene glycol, purified water, sodium benzoate, sucrose, and xanthan gum

Questions or comments?

Call **732-314-4550** from 9AM to 5PM EST, Monday - Friday.

children's

ibuprofen

Oral Suspension (NSAID)

For Ages 2 to 11 Years

NDC 63868-795-04

QC

QUALITY CHOICE **See New Warnings**

Compare to the active ingredient in Children's Motrin®

children's
ibuprofen

Oral Suspension (NSAID)
100 mg per 5 mL

Pain Reliever/Fever Reducer

8 HRS Lasts up to
8 Hours

For ages 2 to 11 years
Alcohol Free

Original Berry
Flavor

4 fl oz (118 mL)

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

** This product is not manufactured or distributed by McNeil
Consumer Healthcare, distributor of Children's Motrin®.

BX-117

Distributed by C.D.M.A., Inc. ©
43157 W 9 Mile Rd
Novi, MI 48375
www.qualitychoice.com
Questions: 800-935-2362

4 OZ



Drug Facts (continued)
■ 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 ■ check wall before using

Drug Facts (continued)
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 printed bottle neckband is broken or missing ■ see bottom panel for lot number and expiration date
Inactive ingredients Acesulfame potassium, anhydrous citric acid, carboxymethylcellulose sodium, D&C Yellow #10, FD&C Red #40, flavors, glycerin, microcrystalline cellulose, polysorbate 80, propylene glycol, purified water, sodium benzoate, sucrose, and xanthan gum
Questions or comments? Call 732-314-4550 from 9 AM to 5 PM EST, Monday - Friday.

** This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Motrin®.

BX 117

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

NDC 63868-795-04

QC
QUALITY
CHOICE

See New Warnings

Compare to the
active ingredient in
Children's Motrin***

Children's
Ibuprofen
Oral Suspension (NSAID)
100 mg per 5 mL

Pain Reliever/Fever Reducer

8 HRS Lasts up to

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)	Purpose
Ibuprofen 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. 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	

■ DRINK WITH LIQUID ONLY
 ■ 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



Distributed by C.D.M.A., Inc.
 43157 W 9 Mile Rd
 Novi, MI 48375
 www.qualitychoice.com
 Questions: 800-935-2362

8 Hours

For ages 2 to 11 years
 Alcohol Free

Original Berry Flavor



4 fl oz (118 mL)



6 35515 99578 9

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

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

Drug Facts
Active ingredient (in each 5 mL)
 Ibuprofen 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. **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

NDC 63868-795-04

QC QUALITY CHOICE

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

4 fl oz (118 mL) Original Berry Flavor

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

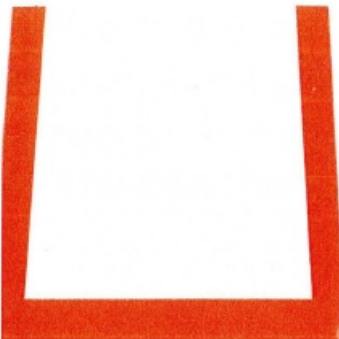
Ask a doctor before use if ■ stomach bleeding warning applies to your child ■ child has a history of stomach problems, such as heartburn ■ child has problems or serious side effects from taking pain relievers or fever reducers ■ child has not been drinking fluids ■ child has lost a lot of fluid due to 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



UR-158



Drug Facts (continued)

- 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

Drug Facts (continued)

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 printed bottle neckband is broken or missing
- see bottom panel for lot number and expiration date

Inactive ingredients
 Acesulfame potassium, anhydrous citric acid, carboxymethylcellulose sodium, D&C Yellow #10, FD&C Red #40, flavors, glycerin, microcrystalline cellulose, polysorbate 80, propylene glycol, purified water, sodium

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



NDC 63868-795-04

See New Warnings

Compare to the active ingredient in Children's Motrin***

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)	Purpose
Ibuprofen 100 mg (NSAID)*.....	Pain reliever/fever reducer

Uses temporarily:

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

- 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 6-8 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
72-85 lbs	11 years	15 mL

*or as directed by a doctor

benzoate, sucrose, and xanthan gum

Questions or comments?
Call 732-314-4550 from 9 AM to 5 PM EST, Monday - Friday.

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BX 117



Distributed by C.D.M.A., Inc.
43157 W 9 Mile Rd
Novi, MI 48375
www.qualitychoice.com
Questions: 800-935-2362

Children's Ibuprofen

Oral Suspension (NSAID)
100 mg per 5 mL

Pain Reliever/Fever Reducer

8 HRS Lasts up to 8 Hours

For ages 2 to 11 years
Alcohol Free

Original Berry Flavor



4 fl oz (118 mL)



■ 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, liver cirrhosis, kidney disease, or had a stroke

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

Drug Facts

Active ingredient (in each 5 mL)

Ibuprofen 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. **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

Purpose

NDC 63868-795-04

QC QUALITY CHOICE

Children's Ibuprofen

Oral Suspension (NSAID)
100 mg per 5 mL

Pain Reliever/Fever Reducer

4 fl oz (118 mL) Original Berry Flavor

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



LR-158



8 OZ

Children's Ibuprofen

Oral Suspension (NSAID)

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) **Purpose**

Ibuprofen 100 mg (NSAID)¹..... Pain reliever/²fever reducer
¹nonsteroidal 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
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- 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 5 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

Drug Facts (continued)

- 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
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 ■ replace original bottle cap to maintain child resistance

Dosing Chart

Weight (lb)	Age (yr)	Dose (mL)*
under 24	under 2 years	ask a doctor
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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 printed bottle neckband is broken or missing
 ■ see bottom panel for lot number and expiration date

Inactive ingredients
 Acacia, dextrose, hydroxyethylcellulose, hydroxypropylcellulose, polyethylene glycol, purified water, sodium benzoate, sucrose, and xanthan gum

Questions or comments?
 Call 732-314-4850 from 9 AM to 5 PM EST, Monday - Friday.

**This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Motrin®.

Distributed by C.D.M.A., Inc.
 43157 W 9 Mile Rd
 Novi, MI 48375
 www.qualitychoice.com
 Questions: 800-935-2362 BX-119

100 mg per 5 mL

For Ages 2 to 11 Years

NDC 63868-795-08



See New Warnings

Compare to the active ingredient in Children's Motrin®

Children's Ibuprofen

Oral Suspension (NSAID)
 100 mg per 5 mL

Pain Reliever/Fever Reducer

8 HRS Lasts up to 8 Hours

For ages 2 to 11 years
 Alcohol Free

Original Berry Flavor



8 fl oz (237 mL)

NDC 63868-795-08



See New Warnings

Compare to the active ingredient in Children's Motrin®

Children's Ibuprofen

Oral Suspension (NSAID)
 100 mg per 5 mL

Pain Reliever/Fever Reducer

8 HRS Lasts up to 8 Hours

For ages 2 to 11 years
 Alcohol Free

Original Berry Flavor



8 fl oz (237 mL)



6 35515 99577 2

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

Drug Facts

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

Ibuprofen 100 mg (NSAID)¹..... Pain reliever/²fever reducer
¹nonsteroidal 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 redness ■ 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

NDC 63868-795-08



Children's Ibuprofen

Oral Suspension (NSAID)
 100 mg per 5 mL

Pain Reliever/Fever Reducer

8 fl oz (237 mL) Original Berry Flavor

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 below. 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



LR-160
 6 35515 99577 2

PEEL HERE

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) Purpose
Ibuprofen 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.

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
has bloody or black stools
has stomach pain that does not get better

Drug Facts (continued)

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 6-8 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
72-85 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 printed bottle neckband is broken or missing
see bottom panel for lot number and expiration date

Inactive ingredients
Acesulfame potassium, anhydrous citric acid, carboxymethylcellulose sodium, D&C Yellow #10, FD&C Red #40, flavors, glycerin, microcrystalline cellulose, polyethylene glycol, purified water, sodium benzoate, sucrose, and xanthan gum

Questions or comments?
Call 732-314-4050 from 9 AM to 5 PM EST, Monday - Friday.
** This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Motrin®.

QUALITY CHOICE GUARANTEED
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43157 W 9 Mile Rd
Novi, MI 48375
www.qualitychoice.com
Questions: 800-935-2362 BX-119

Children's Ibuprofen

Oral Suspension (NSAID)
100 mg per 5 mL

For Ages 2 to 11 Years

NDC 63868-795-08



See New Warnings

Compare to the active ingredient in Children's Motrin***

Children's Ibuprofen

Oral Suspension (NSAID)
100 mg per 5 mL

Pain Reliever/Fever Reducer

8 HRS Lasts up to 8 Hours

For ages 2 to 11 years
Alcohol Free

Original Berry Flavor



8 fl oz (237 mL)

NDC 63868-795-08



See New Warnings

Compare to the active ingredient in Children's Motrin***

Children's Ibuprofen

Oral Suspension (NSAID)
100 mg per 5 mL

Pain Reliever/Fever Reducer

8 HRS Lasts up to 8 Hours

For ages 2 to 11 years
Alcohol Free

Original Berry Flavor



8 fl oz (237 mL)



6 35515 99577 2

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

Drug Facts

Active ingredient (in each 5 mL) Purpose
Ibuprofen 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. 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

NDC 63868-795-08



Children's Ibuprofen

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

8 fl oz (237 mL) Original Berry Flavor

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

any of the following signs of stomach bleeding:
feels faint
vomits blood
has bloody or black stools
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
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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.
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
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48-59 lbs	6-8 years	10 mL
60-71 lbs	9-10 years	12.5 mL



LP-160

55515 99577 2

PEEL HERE

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

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

72-95 lbs 11 years 15 mL
*or as directed by a doctor



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) **Purpose**
Ibuprofen 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 redness ■ 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)

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

Drug Facts (continued)

■ 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
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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 printed bottle neckband is broken or missing
■ see bottom panel for lot number and expiration date

Inactive ingredients
Acacia, croscarmellose sodium, croscarmellose sodium, DSC Yellow #10, FD&C Red #40, flavor, glycerin, microcrystalline cellulose, polyethylene glycol, purified water, sodium benzoate, sucrose, and xanthan gum

Questions or comments?
Call 732-314-4950 from 9 AM to 5 PM EST, Monday - Friday.

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Motrin®.

Distributed by C.D.M.A., Inc.®
43157 W 9 Mile Rd
Novi, MI 48375
www.qualitychoice.com
Questions: 800-935-2362 BX-119

Children's Ibuprofen

Oral Suspension (NSAID)
100 mg per 5 mL

For Ages 2 to 11 Years

NDC 63868-795-08



See New Warnings

Compare to the active ingredient in Children's Motrin®**

Children's Ibuprofen

Oral Suspension (NSAID)
100 mg per 5 mL

Pain Reliever/Fever Reducer



For ages 2 to 11 years
Alcohol Free

Original Berry Flavor



8 fl oz (237 mL)

NDC 63868-795-08



See New Warnings

Compare to the active ingredient in Children's Motrin®**

Children's Ibuprofen

Oral Suspension (NSAID)
100 mg per 5 mL

Pain Reliever/Fever Reducer



For ages 2 to 11 years
Alcohol Free

Original Berry Flavor



8 fl oz (237 mL)



6 35515 99577 2

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Drug Facts

Active ingredient (in each 5 mL) **Purpose**
Ibuprofen 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,



NDC 63868-795-08

Children's Ibuprofen

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

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

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especially in people allergic to aspirin. Symptoms may include:
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 ■ 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

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
72–85 lbs	11 years	15 mL

*or as directed by a doctor



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CHILDRENS IBUPROFEN

ibuprofen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-795
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
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)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	orange	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-795-04	1 in 1 CARTON	12/15/2020	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:63868-795-08	1 in 1 CARTON	12/15/2020	
2		237 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	ANDA210602	12/15/2020	

Labeler - Chain Drug Marketing Association, Inc. (011920774)

Registrant - AptaPharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(63868-795)

Revised: 12/2023

Chain Drug Marketing Association, Inc.