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 asevere 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
36-47 lbs 48-59 lbs 60-71 lbs	4-5 years 6-8 years 9-10 years	7.5 mL 10 mL 12.5 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 SPM 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 indormation 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

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4 OZ







 mL = milliter
 mL = milliter
 find right dose on chart. If possible, use weight to dose; otherwise use age.
 use only enclosed dosing oup. Do not use any other dosing device.

if needed, repeat dose ev y 6-8 hours
do not use more than 4 times a day
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Posture 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

COARAMITO

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



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 excompanied by high fever, headache, nausea, and verniting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 wars of ane unless discated by doctor. years of age unless directed by doctor.

Do not use

if the child has ever had an allergic reaction to Ibuprofer or any other pain reliever/fever reducer right before or after heart surgery

Ask a doctor before use if

- 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 hold before the been a fluid could be completed to the child has lost a lot of fluid due to vomiting or diarrhea

 child has blood begone been dieses fluir

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)

Purpose

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

onsteroidal anti-inflammatory drug *nonsteroidal anti-inflammatory drug

**Uses* temporarily: ** relieves minor aches and pains due to the common cold, flu, sore throat, dache 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



Original Berry Flavor

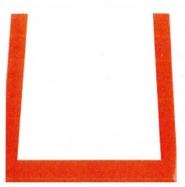
containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ takes more or for a longer time than directed. Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if 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 effeventiever 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 reflievers 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 stoke 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 a 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 • sturred 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



턡



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

Drug Facts (continued)

- Other information

- acah 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 Rad #40, fawors, glycerin, microcrystalline cellulose, polysorbate 80, propylene glycol, purified water, sodium



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

buprofen 100 mg (NSAID)* nonsteroidal anti-inflammatory drug fever reduce

Uses temporarily:
■ relieves minor aches and pains due to the common cold,
flu sone 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

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 = millitter

 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 ev. by 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

zoate, 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®.

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www.qualitychoice.com Questions: 800-935-2362

Novi, MI 48375

CUARANTE

children's Ibuprofen

Oral Suspension (NSAID) 100 mg per 5 mL

Pain Reliever/Fever Reducer



For ages 2 to 11 years Alcohol Free



more than directed or for longer than directed. Some throat warning: Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and verniting 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.

reduces fever

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to sestin. Some

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

If an allergic reaction occurs, atop 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.

In has had stomach uters or bleeding problems

takes a blood thinning (anticoagulant) or steroid drug

takes other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprefer, nearows. or others)

nonprescription NS-VIUs laspinn, ibuproten, naproxen, or others)
■ takes more or for a longer time than directed Heart attack and stroke warning: NS-IDs, except aspirin, increase the risk of heart attack, tear failure, and stroke. These can be fatal. The risk is higher if you use execution directed of risk beneath that did that

more than directed or for longer than directed.

Warnings

Do not use

if the child has ever had an allergic reaction to Ibuprofer

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

■ child has problems or serious side effects from taking

child has problems or serious side effects from taking pain relieves or fever recluvers
 child has not been drinking fluids
 child has lost a lot of fluid due to vomiting or d'arrhea
 child has high blood pressure, hearf 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)

Purpose

lbuprofen 100 mg (NSAID)*..... Pain reliever/ fever reducer onsteroidal anti-inflammatory drug

Uses temporarily: relieves minor aches and pains due to the common cold, flu, sore throat, eadache 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: In has had stomach ulcers or bleeding problems • takes a blood thinning (anticoagulant) or steroid drug • takes other drugs

NDC 63868-795-04 QC children's Ibuprofen Oral Suspension (NSAID) 100 mg per 5 mL Pain Rellever/Fever Reducer

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 a if the child has ever had an allergic reaction to Ibuprofen or any other pain reliever/lever 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 stoke ■ 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 a taking any other drug When using this product a 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 a 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







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) Purpos uprofen 100 mg (NSAID) ionsteroidal anti-inflamo

Uses temporarily:

relieves minor aches and pains due to the common cold, flu, so threat, headache and bosthache
reduces ferer

- Warnings
 Allergy alert: buprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

 hinks:
 tacal swelling:
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 reah:
 in allergic reaction occurs, stop use and seek medical help right anos.

ach bleeding warning: This product contains an NSAID, whice ause severe stomach bleeding. The chance is higher if your

andid.

Best had stomach uicers or bleeding problems

Lakes a blood thinning (ankinoagularif or sterried drug

Lakes other ducy accutating perception or negrezoription

NSADs (asprin, lubprofon, negrosse, or others)

Lakes other dors or a larger sime than directed

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ected. or throat warning: Severe or persistent sore throat or sore throat companied by high fever, headache, nausea, and vomiting may be convert warming: Severe or persistent some times or some times, impanied by high fever, headache, nausea, and vomiting may be use. Consult doctor promptly. Do not use more than 2 days or inister 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
- right before or after heart surgery

- Ask a doctor before use if stomach bleeding woming applies to your child child has a history of stomach problems, such as heartburn child has problems or serious side effects from taking
- critid has problems or serious side effects from taking pain relixorers or fever reducers child has not been drinking hidds child has bet a lot of fluid due to vomiting or diarrhee child has ship intoid pressure, heart disease, liver crimosis, kidney disease, or had a sincke child has selfment.
- child is taking a diuretic
- chind staking a current skill doctor or pharmacist before use if the child is under a doctor's care for any serious condition taking any other drug

- hen using this product take with food or milk if stomach upset occurs
- top use and sex a doctor if
 child experiences any of the following signs of stemach blooding:
 feels faint
 vamils blood
 has bloody or block stoels
 has stomach pain that does not get better

Drug Facts (continued)

- child has symptoms of heart problems or stroke:

 thest pain trouble breathing

 weakness in one part or side of body

 sturned speech leg swelling

 the child does not get any relief within first day (24 hours) of
 treatment.

treatment # fever or pain gets worse or leads more than 3 days # fever or pain gets worse or leads more than 3 days # reduces or swelling is present in the paint's area # any new symploms appear # any new symploms appear fever for the symploms are not paint for the symploms are

- or contact a Pusson Control Center right away, (1)—out—score

 Directions

 This product does not contain directions or
 complete warnings for adult use

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 1 mill right does on chart. If possible, use weight to dose;
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 1 use enly enclosed design cup. On not use any other
 design down on than 4 lines a day

 1 meted, repeat does every 6-8 hours

 2 on not use more than 4 fines as day

 1 replace original boths cup to maintain child resistance

 Design Chart

 Design Chart

Dosina Chart

	Dooning Unan	
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

- Uther Information

 Leach S mL contains: sodium 2 mg

 state between 20-25°0 (88-77°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
Acesultane potassium, arhydrous citric acid, carboxymethylcellulo
sodium, DSC Pellow #10, POBC Red #40, Texrox, glycerin, microcrystall
carbixos, opforable 80, programs glycol, purified water, aode
berazoele, sucrose, and xardhan 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 McNe Consumer Healthcare, distributor of Children's Motrin®.



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For Ages 2 to 11 Years



NDC 63868-795-08

See New Warnings

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



See New Warnings

Compare to the active ingredient in Children's Motriness

children's **Ibuprofen**

Oral Suspension (NSAID) 100 mg per 5 mL

Pain Reliever/Fever Reducer

Children's Ibuprofen

Oral Suspension (NSAID) 100 mg per 5 mL

Pain Reliever/Fever Reducer



For ages 2 to 11 years Alcohol Free



Lasts up to 8 Hours

For ages 2 to 11 years Alcohol Free







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

**State State Stat

NDC 63868-795-08



Children's Ibuprofen

Oral Suspension (NSAID) 100 mg per 5 mL

Original Berry Flavor

8 il us (237 mb.) Original Berry Flavor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by octor. Do not use il if the child has ever had an allergic resolute in buppofen or any other pain relieverflever reducer = "right before or after heart suppry." Ask a doctor before use if il stomach biseding warning applies to your child = child has a history of storacts problems, such as hearthoun = child has problems or serious side effects from taking pain relievers or freer reducers. = "child has not been diriktion thirds = child has lost a lot of fluid due to vomiting or diarries = child has sing hood pressure, heart disease, liver crimotes, kidney disease, or had a stroke in child has soltime = child has high tool pressure, heart disease, liver crimotes, identify a doctor's care for any serious condition = taking any other drug When using this product = take with food or milk if stomach upset cocurs. Stop use and ask a doctor if = child experiences

any of the following signs of skmach bleeding: • feels faint. • vomits blood • has bloody or black stools • has stemach pain that does not get befor # child has symptoms of heart problems or shoke: • cleet prin • Youtke breathing • weakness in one part or side olderly • shured speech • leg swelling: # # child does not get any relief within first day (24 hours) of treatment # fewer or pain gets worse or less more than 3 days = * rechaess or swelling is present in the perintul area * any new symptoms appear. • Repo not of reach of children. In case of everdose, get medical help or contact a Poison Control Center right away, (1-800-222-1229)

Directions = this product does not contain directions or complete warnings for adult use

warnings for adult use

do not give more than directed shake well before using

ml. = milistine "find right dose on chart below. If possible, use weight to
dose; otherwise use age. = use only endosed 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 * repicce original bottle cap to maintain child resistance

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

15 mL

72-95 lbs 11 years *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

Drug racis	
Active ingredient	Purpose
(in each 5 mL)	
lbuprofen 100 mg (NSAID)*	
"nonsteroidal anti-inflammatory drug	fever reducer

Uses temporarily:

relieves minor aches and pains due to the common cold, flu, so throat, headlache and toothache reduces fever

- Warnings
 Allergy afert: buprolen may cause a severe allergic reaction, especially in people afergic to aspirin. Symptoms may include:

 Inhose
 inhose in accid swelling
 asthmia (wheezing) shock
 skin modification
 if an allergic reaction occurs, slop use and seek medical help right away.

ach bleeding warning: This product contains an NSAID, which

anid:

Bas had stomach utcers or bleeding problems

Balses a blood thinsing (paiscoagularit) or storreid drug

Balses other drugs containing perception or negrecoription

NSADIO (paptin), buprofon, nagrosson, or others)

Balses more or for a longer sime than directed

Person a lands cord ctucke warning NSADIO, except aspirin, increase

He risk of herst altack, heart failure, and stoket. These can be fatal,

bur sisk in higher if you use more than directed or for longer than

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ore throat warning: Severe or persistent sore throat or sore throat
companied by high fever, headache, nausea, and vomiting may be
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- On not use

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- other pain reliever/lever reducer right before or after heart surgery

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 Ask a doutine herbere use if

 stomach bleeding werning applies to your child

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 child has a nishory of stomach problems, such as herrburn

 child has problemer or serious side effects from taking

 gain relievers or sever reducers

 child has not been dininking fluids

 child has not a toof fluid due to vorning or disembe

 child has not been dininking fluids

 child has high blood pressure, heart disease, liver

 chirdosis, kilder glesses, or had a stroke

 child has addition

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- chied has additional chied chied chied chied in the 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
- top use and sek a doctor if
 child experiences any of the following signs of stomach bleeding
 least faint
 vomits blood
 has bloody or block stools
 las stomach pain that does not get better

Drug Facts (continued)

- child has symptoms of heart problems or stroke:

 thest pain trouble breathing
 weakness in one part or side of body
 sturned speech
 leg awelling
 the child does not get any relief within first day (24 hours) of
 treatment.

- treatment

 # dever or pain grets worse or leads more than 3 days

 # redness or swelling is present in the paint's area

 # any new symptoms appear

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 # or possible of children, in case or overdose, get modical help
 or cornact a Poison Centrol Center right away, (1 800 222 1222)

Directions

- this product does not contain directions or

- this product does not contain directions or complete warnings for adult use do not give more than directed shad well before using mt. = milliber find right does on chart. If possible, use weight to dose; otherwise use ago. use only enclosed dosing oup. On 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 ch
- child resists

Dosina Chart

Weight (Ib)	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

Other information

- Unter information

 each 5 mL certains : sodium 2 mg

 stre between 20 25°C (88 77°F)

 do not use if carbon is opened or printed bottle
 nockband is broken or missing

 see bottom panel for lot number and expiration date

Inactive ingredients
Aceatians palasium, anhydrous cinic acid, carbonymethylcellulo
sodium, DSC Pelbur #10, F03C Ped #40, Texors, glycerin, microcrystalli
catalosos, polyonotide 80, prospiane glycol, purified waller, sodiu
berozeale, aucrose, and xarihan 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 McNell 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

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**



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

Children's Ibuprofen

Oral Suspension (NSAID) 100 mg per 5 mL

Pain Reliever/Fever Reducer



Lasts up to 8 Hours

For ages 2 to 11 years

Alcohol Free



Lasts up to

For ages 2 to 11 years Alcohol Free





8 fl oz (237 mL)



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)

Purnose

|buprofen 100 mg (NSAID)*...... *nonsteroidal anti-inflammatory drug .. Pain reliever/ fever reducer

VSes temporally:

Vses temporally:

■ relieves minor aches and pains due to the common cold, flu, sore throat, headachs and toothache ■ reduces fever sore throat, headachs and loofhache = reduces fever Warnings
Altergy afert: buprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

• hives = taclel swelling = asthmat (wheezing) = shock = shick = s NDC 63868-795-08



Children's Ibuprofen

Oral Suspension (NSAID) 100 mg per 5 mL

Original Berry Flavor

The first (227 mb). Original Berry FisVor 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 bupcofen or any other pain relieverfere reducer = "right before or after heart surgery. Ask a doctor before use if # stomach tiseding warning applies to your child = child has a history of stomest problems, such as hearthum = child has problems or serious side effects from taking pain relievers or fever reducers = "child has not been drinking history and the side of the child has high blood pressure, heart disease, lever carhoss, didney desses, or had a strole "shift has softme "dhild is taking a durefic Ask a doctor or pharmacist before use if the child is " under a

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







15 mL





Purpose
Pain reflever/ fever reducer

relieves minor aches and pains due to the common cold, flu, sore throat, headsche and bothache
 reduces fever

temach bleeding warning: This product contains an NSAID, which lay cause severe stomach bleeding. The chance is higher if your

- sid:
 has hed stomach utcers or bleeding problems
 takes a blood thinning disnicoagularity or steroid drug
 takes other drugs containing prescription or nonprescription
 KSADIS (aspirin, libuporten, naproxem, or others)
 takes more or for a larger time than directed
 west attack end choke warning: KSADIS, except aspirin, increases
 erisk of heart attack, heart failure, and stokes. These can be falsal,
 erisk is higher if yeu use more than directed or for longer than
 wested.

recteu.
on threat warning: Severe or persistent sore threat or sore threat cocompanied by high fever, headache, nausea, and vamiting may be enfous. Consult doctor promptly. Do not use more than 2 days or dminister to children under 3 years of age unless directed by doctor.

- Do not use

 if the child has ever had an allergic reaction to Euprofen or any
- other pain reliever/lever reducer right before or after heart surgery
- Ask a doctor before use if
- ask a doctor before use if stomoch testomoch t

- Ask a doctor or pharmacist before use if the child is

 under a doctor's care for any serious condition

 taking any other drug

- taking any orner urug
 When using this product
 take with food or milk if stomach upset occurs
- long use and ask a doctor if child experiences any of the following signs of stomach blooding feels faint vomits blood child experiences any of the following signs or s
 feels faint vomits bloo
 has bloody or block steels
 has stomach pain that does not get better

Drug Facts (continued)

• The child does not get any fewer written man use yet moving an treatment.
• Ever or pain gets worse or leads more than 3 days reddress or writting is present in the painful area.
• any new symptoms appear
• any new symptoms appear
• contact a Puison Centrol Center right away. (1 – 800 – 222 – 1222)

- Directions

 *Bis product does not contain directions or complete warmings for adult use

 do not give more than directed

 shake well before using

 m.e. milliber

 find right does on chart. If possible use weight
- mil. = millitier fight dose on chart. If possible, use weight to dose; otherwise use age. use only enclosed dosing cup. Do not use any other

of use more than	e every 6-8 hours 4 times a day cap to maintain o Dosing Char	hild resistance
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

- Other information

 sech 5 ml. contains: sodium 2 mg
 stare between 20–25° (58–77°)
 do not use if carton is opened or primet bottle
 neckband is broken or missing
 see bottom panel for lot number and expiration date

Inactive ingredients
Acesultane potassium, arhydrous citric acid, carboxymethylcellula
sodium, DSC Pellow #10, FDGC Red #40, Itavors, glycerin, microcrystalli
callulosa, polynorhale 80, propylane slycol, purified walta; sodiu
bercelok, sucrese, and sarthan 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 McNei lonsumer Healthcare, distributor of Children's Motrin®.



Distributed by C.D.M.A., Inc.® 43157 W 9 Mile Rd Novi, MI 48375 W 9 Mile Rd Novi, MI

BX-119

children's **Ibuprofen**

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***



See New Warnings

active ingredient in Children's Motrin***

children's **Ibuprofen**

Oral Suspension (NSAID) 100 mg per 5 mL

Pain Reliever/Fever Reducer

Ibuprofen Oral Suspension (NSAID)

Children's

100 mg per 5 mL

Pain Reliever/Fever Reducer



For ages 2 to 11 years Alcohol Free



Lasts up to 8 Hours

For ages 2 to 11 years Alcohol Free





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

VSes temporarily:

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

Warnings Allergy alert: Ibuprolen may cause a severe allergic reaction,



any of the following signs of stomach bleeding: . feels faint . . womits blood any or the rotewing signs of stimulat bleeding: *Best start. * wmits blood or bank sloody or black slools * has stimulate plant does not get before a child has symptoms of heart problems or shocke: * clest poin * froutile breathing * weakness in one part or side of body * situred speech * leg swelling. * Bho child does not get any retief within first darg? * hours) of treatment * flower or pain gets worse or less than one than 3 days. * encloses or swelling is present in the painful area * any new symptoms appear * encloses or swelling is present in the painful area * any new symptoms appear * encloses or swelling is present in the painful area * any new symptoms appear * encloses or swelling is present in the painful area. * Enclose of the discount of the stimulation of the symptoms area. * The symptoms of the symptom

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 = shelo well before using

m.l. = milliatre = find right does on chart below. If possible, use weight to
close; otherwise use age. = see only enclosed doesing cup. Do not use any
other doesing device. = if needed, repeat does every 6–8 hours = do not use

especially in people allergic to aspirin. Symptoms may include:

• hives • facial swelling • asthma (wheezing) • shock • skin reddening • rash • bilaters. If an allergic maction occurs, step use and seek medical help right away. Stomach bleeding warning: This product contains an ISADI, which may cause severe stomach bleeding. The chance is higher if your child:

• hus heat stomach electrs or bleeding problems • lakes at blood thinning lambcagulanth or steproid drug • takes other drugs containing prescription or nonprescription NSADIs (aspirin, buyrofen, rapresse, or others) • takes mere or for a longer time then directed. Heart attack and stroke warning: NSADIs, except aspirin, increase the risk of heart attack, heart fallure, and stroke. These can be fatal. The risk is higher if you use more than directed. Shore throat warning: Severe or praisitum some threat or sere throat accompanied by high fever, headache, nausea, and vorniting may be serious. Constall doctor

promptly. Do not use more than 2 days or administre to children under 3 years of age unless directed by doctor. Do not use "if the child has ever had an allergic resolution to bucycroft or any other pain reliever/there reducer " eight befrer or after hest surgery. Ask a doctor before use if " elamnach ideading warning applies to you child" e hidd has a history of atomach problems, such as hearthoun " child has lost a lot of fluid due to vomiting or derintes a child has held host posture, heart disease, her crimtosis, kidney disease, or had a strole or child has softim a "child in se lotted a doctor or pharmacist before use if the child is " under a doctor" care for any serious condition " tasking any other drug When using this product. " Jake with flood or milk if stomach upset cocurs Stop use and ask a doctor if " child experiences

more than 4 times a day ■ replace original bottle cap to maintain child

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	
as as diseased	hora desire		





res

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: WK2XYI10QM) (IBUPROFEN - UNII: WK2XYI10QM) IBUPROFEN 100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 230V7305G9)	

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)

CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)

D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)
FD&C RED NO. 40 (UNII: WZB9127XOA)

GLYCERIN (UNII: PDC6A3C0OX)

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

POLYSORBATE 80 (UNII: 60ZP39ZG8H)
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			

P	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.