

Drug Facts (continued)

Warnings

Allergy alert ■ ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin.

Symptoms may include: ■ hives ■ facial swelling ■ difficulty breathing

■ 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 a 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

Drug Facts (continued)

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
- find right dose on chart below. If possible, use weight to dose; otherwise use age.
- mL = milliliter
- measure with the dosing device provided. Do not use with any other device.
- dispense liquid slowly into the child's mouth, toward the inner cheek
- if needed, repeat dose every 6-8 hours
- do not use more than 4 times a day

Dosing Chart		
Weight (lb)	Age (mos)	Dose (mL)
under 6 mos		ask a doctor
12-17 lbs	6-11 mos	1.25 mL
18-23 lbs	12-23 mos	1.875 mL

Other information

- store between 20-25°C (68-77°F)
- do not use if carton tape imprinted "SAFETY SEAL" or bottle wrap imprinted "SAFETY SEAL" and "USE WITH ENCLOSED DOSING DEVICE ONLY" is broken or missing

Inactive ingredients anhydrous citric acid, carmellose, FD&C red no. 40, flavors, glycerin, polysorbate 80, pregelatinized starch, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum

Questions or comments?
 Call 1-877-895-3665 (toll-free) or 215-273-8755 (colect)

See New Warnings
 NDC 50580-100-18
For Ages 6 Mos. to 23 Mos.

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

Lasts up to 8 hours

Original Berry Flavor
1/2 fl oz (15 mL)

Use only with enclosed syringe.

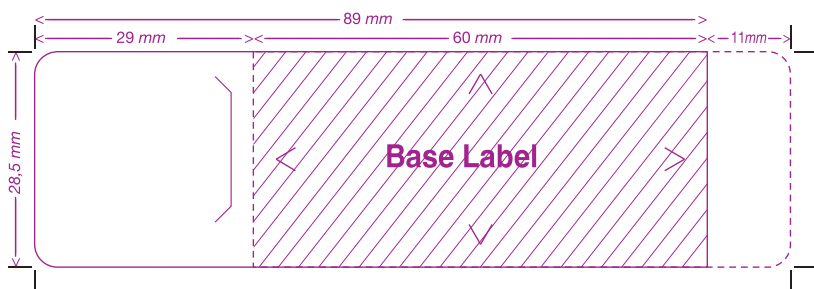
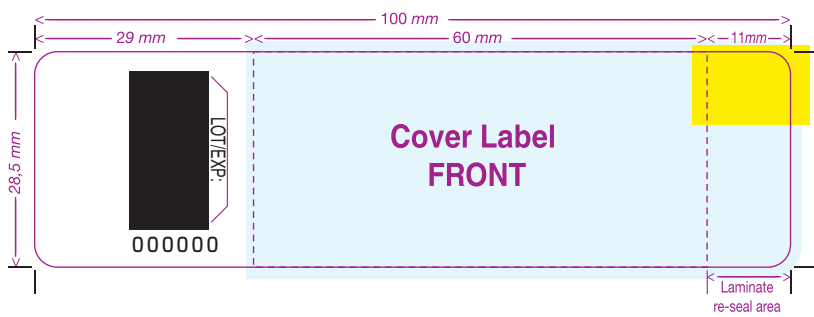
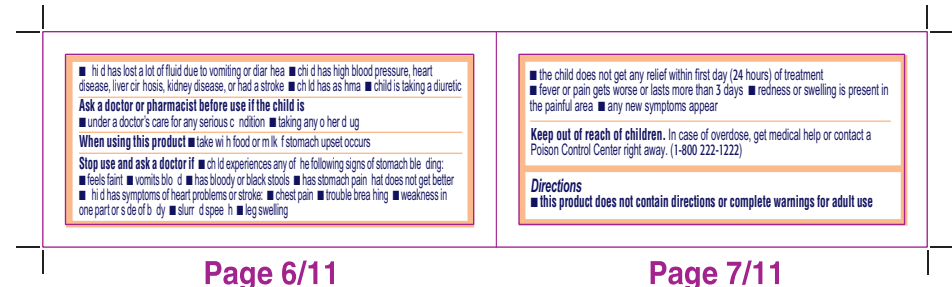
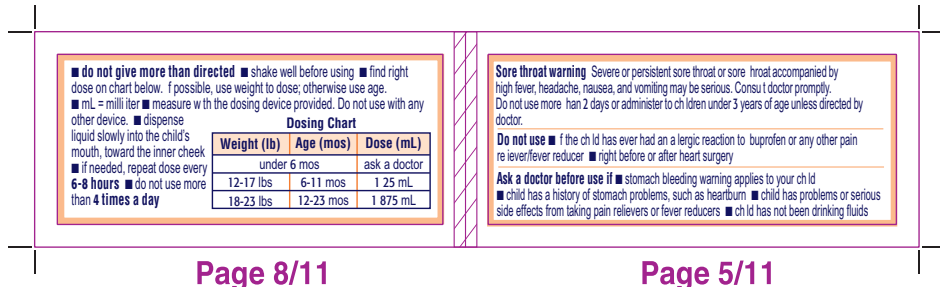
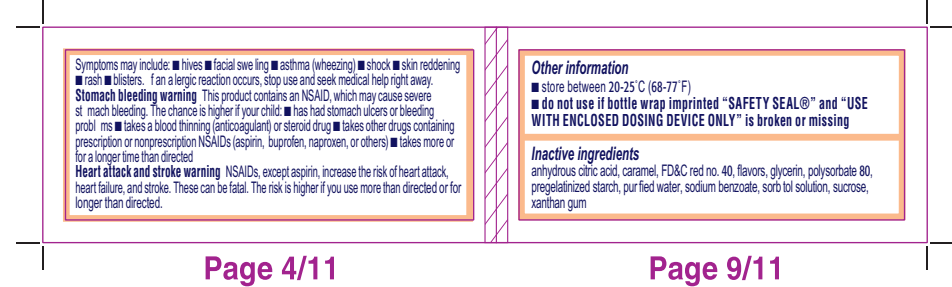
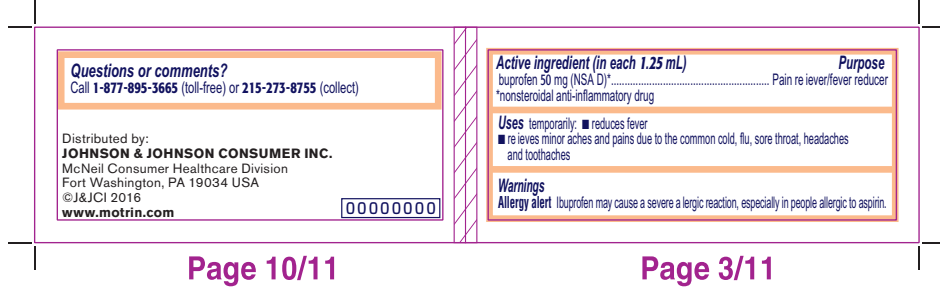
Actual Size

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Distributed by: **JOHNSON & JOHNSON CONSUMER INC.**
 McNeil Consumer Healthcare Division
 Fort Washington, PA 19034 USA ©J&JCI 2016
www.motrin.com



(b) (4)

See New Warnings
NDC 50580-198-50
For Ages 6 Mos. to 23 Mos.

**Concentrated Motrin®
Infants' Drops**
DYE-FREE

contains **Ibuprofen**
Oral Suspension (NSAID)
50 mg per 1.25 mL

Pain Reliever/Fever Reducer

**Lasts up to
8 hours**

Use only with
enclosed syringe.

**Non-Staining
Original Berry Flavor**
1 fl oz (30 ml)

LOT: _____

EXP: _____

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www.motrin.com

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Oral Suspension (NSAID)
50 mg per 1.25 mL

Pain Reliever/Fever Reducer

**Non-Staining
Original Berry Flavor**
1 fl oz (30 ml)

Actual Size

Drug Facts (continued)

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 non-prescription 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 or 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
- child does not get any relief within first day (24 hours) of treatment
- fever or pain gets worse or lasts more than 3 days
- drowsiness or swelling is present in the painful areas
- 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. (800) 222-1222
Directions

- this product does not contain directions or complete warnings for adult use →

Drug Facts (continued)

■ do not give more than directed
 ■ shake well before using
 ■ find right dose on chart below. If possible, use weight to dose, or otherwise use age
 ■ mL = milliliter
 ■ measure with the dosing device provided. Do not use without any of the device.
 ■ dispense liquid slowly into the child's mouth, away from the inner cheek.
 ■ if needed, repeat dose every 6-8 hours
 ■ do not use more than 4 times a day

Dosing Chart

Weight (lb)	Age (mos)	Dose (mL)
under 6 mos		ask a doctor
12-17 lbs	6-11 mos	1.25 mL
8-23 lbs	12-23 mos	1.875 mL

Other information
 ■ store below 20-25°C (68-77°F)
 ■ do not use if carton is opened or carton tape imprinted "SAFETY SEAL" or bottle wrap imprinted "SAFETY SEAL" and "USE WITH ENCLOSED DOSING DEVICE ONLY" is broken or missing

Inactive ingredients anhydrous citric acid, caramel, inositol, glycerin, polyorbate 80, pregelatinized starch, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum

Questions or comments? Call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)



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THE DOSING CHART AND DIRECTIONS APPEARING ON THE FIRST AND LAST PAGE ARE REPEATED FOR YOUR CONVENIENCE. PLEASE READ AND KEEP ALL WARNINGS AND DIRECTIONS TO ENSURE THE PROPER USE OF THIS CONCENTRATED INFANTS' MOTRIN® PRODUCT.

Important Read all product information before using. Keep the box for important information. This product is intended for use in children ages 6 months to 23 months of age.

Active ingredient (in each 1.25 mL)
ibuprofen 50 mg (NSAID)Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Purpose
Pain reliever/fever reducer

Uses temporarily:

- reduces fever
- relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches

Directions ■ this product does not contain directions or complete warnings for adult use ■ do not give more than directed ■ shake well before using ■ find right dose on chart below. If possible, use weight to dose; otherwise use age. ■ mL = milliliter ■ measure with the dosing device provided. Do not use with any other device. ■ dispense liquid slowly into the child's mouth, toward the inner cheek ■ if needed, repeat dose every 6-8 hours ■ do not use more than 4 times a day

Concentrated Motrin® Infants' Drops
contains ibuprofen Oral Suspension (NSAID) 50 mg per 1.25 mL
Pain Reliever/Fever Reducer
Non-Staining Original Berry Flavor
1 fl oz (30 mL)

Weight (lb)	Age (mos)	Dose (mL)
under 6 mos		ask a doctor
12-17 lbs	6-11 mos	1.25 mL
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Page 2 **Page 7**

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!!! OPEN to read all Warnings and Directions before use

Directions ■ this product does not contain directions or complete warnings for adult use ■ do not give more than directed ■ shake well before using ■ find right dose on chart below. If possible, use weight to dose; otherwise use age. ■ mL = milliliter ■ measure with the dosing device provided. Do not use with any other device. ■ dispense liquid slowly into the child's mouth, toward the inner cheek ■ if needed, repeat dose every 6-8 hours ■ do not use more than 4 times a day

Concentrated Motrin® Infants' Drops
NDC 50580-198-50
contains ibuprofen Oral Suspension (NSAID) 50 mg per 1.25 mL
Pain Reliever/Fever Reducer
Non-Staining Original Berry Flavor
1 fl oz (30 mL)

Glue Area (glued to base label if only 7 pages needed)

Weight (lb)	Age (mos)	Dose (mL)
under 6 mos		ask a doctor
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Do not use

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

Ask a doctor before use if

- stomach bleeding warning applies to your child
- child has a history of stomach problems, such as heartburn
- child has problems or serious side effects from taking pain relievers or fever reducers
- child has not been drinking fluids
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Stop use and ask a doctor if

- child experiences any of the following signs of stomach bleeding:
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 - has stomach pain that does not get better
- child has symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- child does not get any relief within first day (24 hours) of treatment
- fever or pain gets worse or lasts more than 3 days
- rashes 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

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Page 4 **Page 5**

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Page 6 **Page 3**

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Cover Label BACK

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Base Label

