

MOTRIN INFANTS- ibuprofen suspension/ drops
Johnson & Johnson Consumer Inc.

Motrin ®

Infants'

Drug Facts

Active ingredient (in each 1.25 mL)

Ibuprofen 50 mg (NSAID) ¹

¹ nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses

temporarily:

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

Warnings

Allergy alert

Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin.

Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if 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
- 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 or bottle wrap imprinted with "Sealed For Your Safety" is broken or missing**

Inactive ingredients

anhydrous citric acid, caramel, 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** (collect)

PRINCIPAL DISPLAY PANEL

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)



Drug Facts

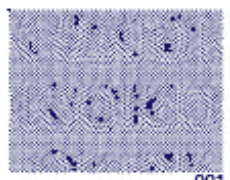
Active ingredient (in each 1.25 mL)
Ibuprofen 50 mg (NSAID)
Pain reliever/fever reducer

Purposes

Uses temporarily:

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

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



001

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

Concentrated
Motrin[®]
Infants' Drops
DYE-FREE



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)

Original Berry Flavor

1 fl oz (30 ml)

Actual Size

LOT:

EXP:

Distributed by: **JOHNSON & JOHNSON CONSUMER INC.**
McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA ©J&JCI 2020
www.motrin.com 30045309

USA
692473
887



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 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

Drug Facts (continued)

- 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 or bottle wrap imprinted with "Sealed For Your Safety" is broken or missing

Inactive ingredients anhydrous citric acid, caramel, flavors, glycerin, polysorbate 80, pregelatinized starch, purified water, sodium benzoate, sorbitol



MOTRIN INFANTS

ibuprofen suspension/ drops

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50580-198 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|------------------|
| IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM) | IBUPROFEN | 50 mg in 1.25 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| CAMEL (UNII: T9D99G2B1R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SORBITOL SOLUTION (UNII: 8KW3E207O2) | |
| SUCROSE (UNII: C151H8M554) | |

XANTHAN GUM (UNII: TTV12P4NEE)

Product Characteristics

| | | | |
|----------|-------------------|--------------|--|
| Color | white (Off white) | Score | |
| Shape | | Size | |
| Flavor | BERRY | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:50580-198-50 | 1 in 1 CARTON | 06/08/2012 | |
| 1 | | 30 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package | | |
| 2 | NDC:50580-198-51 | 1 in 1 CARTON | 06/08/2012 | 06/09/2012 |
| 2 | | 15 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package | | |
| 3 | NDC:50580-198-52 | 2 in 1 PACKAGE | 06/08/2012 | 09/20/2014 |
| 3 | | 1 in 1 CARTON | | |
| 3 | | 30 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA020603 | 09/01/2001 | |

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 2/2024

Johnson & Johnson Consumer Inc.