CHILDRENS IBUPROFEN- ibuprofen suspension TARGET Corporation

Children's Ibuprofen

Drug Facts

Active ingredient (in each 5 mL)

Ibuprofen 100 mg $(NSAID)^1$

Purpose

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.

¹ nonsteroidal anti-inflammatory drug

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 to 8 hours**
- do not use more than 4 times a day
- replace original bottle cap to maintain child resistance

Dosing Chart

Weight (lb)	Age (yr)	Dose (mL)*
under 24	under 2 years	ask a doctor
24-35 lbs	2-3 years	5 mL
36-47 lbs	4-5 years	7.5 mL
48-59 lbs	6-8 years	10 mL
60-71 lbs	9-10 years	12.5 mL
72-95 lbs	11 years	15 mL

^{*} or as directed by a doctor

Other information

- **Store at 20° to 25°C (68° to 77°F)** [see USP Controlled Room Temperature].
- do not use if carton is opened or if bottle wrap imprinted with "SEALED FOR SAFETY" is broken or missing
- see bottom panel of carton for lot number and expiration date

Inactive ingredients

acesulfame potassium, berry flavor natural & artificial, citric acid anhydrous, glycerin, polysorbate 80, pregelatinized modified starch, purified water, sodium benzoate, sucrose, xanthan gum

Questions?

Call 1-800-910-6874

Distributed by Target Corporation Minneapolis, MN 55403

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

NDC 11673-349-08

see new warnings

Compare to active ingredient in Children's Motrin® Dye-Free*

dye-free children's

ibuprofen

oral suspension, USP

100 mg per 5 mL

pain reliever/fever reducer

(NSAID)

alcohol free

DOSAGE CUP

INCLUDED

LASTS UP TO

8

HOURS

BERRY

FLAVOR

AGES

2–11

YEARS

up&up

4 FL OZ (120 mL)

dye-free children's ibuprofen

oral suspension, USP 100 mg per 5 mL pain reliever/fever reducer (NSAID)





AGES

2-11

YEARS

NDC 11673-349-08

see new warnings

Compare to active ingredient in Children's Motrin® Dye-Free*

dye-free children's ibuprofen

oral suspension, USP 100 mg per 5 mL pain reliever/fever reducer (NSAID)

alcohol free





up&up



BERRY

AGES

2–11

YEARS

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:

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blisters

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- 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

NO VARNISH/ NO AQ NO COPY / NO COLOR THIS FLAP FOR LOT # AND EXP DATE PRINT T181C B98.2 ENG19.59



NO VARNISH ON THIS FLAP

Drug Facts (continued)

Ask a doctor before use if

- · stomach bleeding warning applies to your child
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Drug Facts (continued)

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Inactive ingredients

acesulfame potassium, berry flavor natural & artificial, citric acid anhydrous, glycerin, polysorbate 80, pregelatinized modified starch, purified water, sodium



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Questions?

Call 1-800-910-6874

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benzoate, sucrose, xanthan gum

C-001472-01-061

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CHILDRENS IBUPROFEN

ibuprofen suspension

Product Information

Product Type HUMAN OTC DRUG NDC:11673-349 Item Code (Source)

ORAL **Route of Administration**

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength Ibuprofen (UNII: WK2XYI10QM) (Ibuprofen - UNII:WK2XYI10QM) Ibupro fen 100 mg in 5 mL

Inactive Ingredients Ingredient Name Strength acesulfame potassium (UNII: 23OV73Q5G9) anhydrous citric acid (UNII: XF417D3PSL) glycerin (UNII: PDC6A3C0OX) polysorbate 80 (UNII: 6OZP39ZG8H) sodium benzoate (UNII: OJ245FE5EU) water (UNII: 059QF0KO0R) sucrose (UNII: C151H8M554) xanthan gum (UNII: TTV12P4NEE)

Product Characteristics			
Color	WHITE (WHITE to OFF-WHITE)	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:11673-349-08	1 in 1 CARTON	10/16/2020			
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product				
2	NDC:11673-349-01	1 in 1 CARTON	10/16/2020			
2		240 mL in 1 BOTTLE; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA209207	06/27/2017		

Labeler - TARGET Corporation (006961700)

Revised: 12/2020 TARGET Corporation