

UP AND UP CHILDRENS IBUPROFEN- ibuprofen tablet, chewable
Target Corporation

Target Corporation Children's Ibuprofen Drug Facts

Active ingredient (in each chewable tablet)

Ibuprofen 100 mg (NSAID)*

*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

- mouth or throat burning may occur; give with food or water
- 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

- **chew or crush tablets completely before swallowing**
- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed**
- find right dose on chart below. If possible, use weight to dose; otherwise use age.
- if needed, repeat dose every **6-8 hours**
- do not use more than **4 times a day**

| Dosing Chart | | |
|---------------------|-----------------|----------------|
| Weight (lb) | Age (yr) | Tablets |
| under 24 | under 2 | ask a doctor |
| 24-35 | 2-3 | 1 |
| 36-47 | 4-5 | 1 ½ |
| 48-59 | 6-8 | 2 |
| 60-71 | 9-10 | 2 ½ |
| 72-95 | 11 | 3 |

Other information

- phenylketonurics: contains phenylalanine 6 mg per tablet
- store between 20-25°C (68-77°F)
- **do not use if printed seal under cap is broken or missing**

Inactive ingredients

acesulfame potassium, ammonium glycyrrhizin, aspartame, carnauba wax, croscarmellose sodium, FD&C yellow no. 6 aluminum lake, hypromellose, magnesium stearate, mannitol, natural and artificial flavors, silicon dioxide, sodium lauryl sulfate, soybean oil, succinic acid

Questions?

Call 1-888-547-7400

Package/Label Principal Display Panel

Compare to active ingredient in Children’s Motrin®

children's

ibuprofen

chewable tablets, 100 mg

pain reliever/fever reducer (NSAID)

chewables

AGES 2 TO 11 YEARS

LASTS UP TO 8 HOURS

ORANGE FLAVOR

24 TABLETS

24 CHEWABLE TABLETS

chew or crush tablets completely before swallowing

40102 UM C4

CODE AREA



KEEP CARTON FOR REFERENCE

NDC 11673-593-62
Compare to active ingredient in Children's Motrin[®]

children's ibuprofen

chewable tablets, 100 mg
pain reliever/fever reducer (NSAID)
chewables



AGES
2 TO 11
YEARS

LASTS UP TO
8
HOURS



ORANGE
FLAVOR

24
TABLETS

24 CHEWABLE TABLETS

chew or crush tablets completely before swallowing

Drug Facts (continued)

Do not use if the child does not get any relief within the first day (24 hours) of treatment or if fever or pain gets worse or lasts more than 3 days. Do not use if redness or swelling is present in the painful area or if 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
Chew or crush tablets completely before swallowing. This product does not contain dextrose or complete warnings for adults use.

Do not give more than directed. Find right dose on chart below if possible, use weight to dose, otherwise use age.

If needed, repeat dose every 6-8 hours. Do not use more than 4 times a day.

| Dosing Chart | | |
|--------------|----------|--------------|
| Weight (lb) | Age (yr) | Tablets |
| under 24 | under 2 | ask a doctor |
| 24-35 | 2-3 | 1 |
| 36-47 | 4-5 | 1½ |
| 48-59 | 6-8 | 2 |
| 60-71 | 9-10 | 2½ |
| 72-85 | 11 | 3 |

Drug Facts

Read the important information before using. Keep this box for important information. This product is for children only.

Active ingredient (in each chewable tablet): *Purposes* ibuprofen (100 mg NSAID).....Pain reliever/fever reducer
Nonsteroidal anti-inflammatory drug

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 redness, rash, or blisters.

If an allergic reaction occurs, stop use and seek medical help right away. Stop use if bleeding warning, the production of an NSAID, which may cause serious stomach bleeding. The chance is higher if your child has had stomach ulcers or bleeding problems.

It may cause dizziness or lightheadedness. The chance is higher if your child takes other drugs containing aspirin or ibuprofen or NSAIDs (aspirin, ibuprofen, naproxen, or others).

It may cause dizziness or lightheadedness. The chance is higher if your child takes more or for a longer time than directed.

Heart attack and stroke warnings: If you, or your child, experience 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.

See first warnings: Severe or persistent sore throat, or swelling not 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 6 years of age unless directed by doctor.

Drug Facts (continued)

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: child has had bleeding warning anytime by 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 been too hot due to working or diarrhea; child has high blood pressure, heart disease, liver or kidney disease, or had asthma; child has asthma; child is taking aspirin.

Ask a doctor or pharmacist before use if the child is under a doctor's care for any serious condition or taking any other drug.

When using this product: mouth or throat burning may occur; give with food or water; 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: fresh, vomit, blood, or bloody or black stool; 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; blurred speech; or difficulty swallowing.

Drug Facts (continued)

Other information

- phenyltolonitrile: contains phenyltolonitrile 6 mg per tablet
- store between 20-25°C (68-77°F)
- do not use if printed seal under cap is broken or missing

Inactive ingredients: acesulfame potassium, ammonium glycyrrhizate, aspartame, camouba wax, croscarmellose sodium, FD&C yellow no. 6 aluminum lake, hypromellose, magnesium stearate, mannitol, natural and artificial flavors, silicon dioxide, sodium lauryl sulfate, soybean oil, succinic acid

Questions? Call 1-888-547-7400

This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Children's Motrin[®].

094 01 0786 R02 ID225432
Distributed by Target Corporation
Minneapolis, MN 55403

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UP AND UP CHILDRENS IBUPROFEN

ibuprofen tablet, chewable

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:11673-593 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) | IBUPROFEN | 100 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | |
| AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C) | |
| ASPARTAME (UNII: Z0H242BBR1) | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MANNITOL (UNII: 3OWL53L36A) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| SOYBEAN OIL (UNII: 241ATL177A) | |
| SUCCINIC ACID (UNII: AB6MNQ6J6L) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|----------|
| Color | ORANGE | Score | 2 pieces |
| Shape | ROUND | Size | 13mm |
| Flavor | ORANGE | Imprint Code | L461 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:11673-593-62 | 1 in 1 CARTON | 07/31/2019 | |
| 1 | | 24 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 | ANDA076359 | 07/31/2019 | |

Labeler - Target Corporation (006961700)

Revised: 10/2022

Target Corporation