

REXALL IBUPROFEN- ibuprofen tablet, chewable
Dolgenercorp, LLC

Dolgenercorp, LLC Ibuprofen Tablets 100 mg 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 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, D&C red no. 27 aluminum lake, FD&C blue no. 1 aluminum lake, hypromellose, magnesium stearate, mannitol, natural and artificial flavors, silicon dioxide, sodium lauryl sulfate, soybean oil, succinic acid

Principal Display Panel

Chewables For Ages 2 to 11

Grape FLAVOR

LASTS UP TO 8 HOURS

Children’s Ibuprofen

Chewable Tablets 100 mg

Pain Reliever/Fever Reducer (NSAID)

Chew or crush tablets completely before swallowing

24 Chewable Tablets

52162 CF C5

GEORGE ALEXANDER



A0129

KEEP CARTON FOR REFERENCE

Important: Read all product information before using. Keep this box for important information. This product is for children only.

Drug Facts

Active ingredient (in each chewable tablet) **Purposes**
Ibuprofen 100 mg (NSAID)¹..... Pain reliever/fever reducer
¹nonsteroidal 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
■ sores ■ 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 chances are higher if you child:
■ has had stomach ulcers or bleeding problems
■ takes a blood thinning (anticoagulant) or steroid drug
■ takes other drugs containing aspirin, ibuprofen, naproxen, or others)
■ 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. Some throat warning: Severe or persistent sore throat or some throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 24 days or administer to children under 3 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
■ 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 a fast lot of fluid due to vomiting or diarrhea
■ child has a high blood pressure, heart disease, heart chafosis, 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
■ avoid or third burning may occur; give with food or water
■ take with food or milk if stomach upset occurs
■ Stop use and ask doctor if
■ child experiences any of the following signs of stomach bleeding:
■ tests that ■ vomits blood ■ uses bloody or black stools
■ has so much pain that does not get better
■ child has symptoms of heart problems or stroke:
■ chest pain ■ trouble breathing
■ weakness in one part of side of body
■ slurred speech ■ leg swelling

Drug Facts (continued)
■ The child does not get any relief within first 24 hours of treatment
■ Fever or pain gets worse or lasts more than 3 days
■ Redness or swelling is present in the part of 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

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48-59	6-8	2
60-71	9-10	2½
72-95	11	3

Drug Facts (continued)
■ Do not use if child has ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer
■ Right before or after heart surgery
■ 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 a fast lot of fluid due to vomiting or diarrhea
■ Child has a high blood pressure, heart disease, heart chafosis, 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

Drug Facts (continued)

Other important information
■ Do not use if child has ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer
■ Right before or after heart surgery
■ 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 a fast lot of fluid due to vomiting or diarrhea
■ Child has a high blood pressure, heart disease, heart chafosis, 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

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GLUTEN FREE

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Chewables For Ages 2 to 11

LASTS UP TO 8 HOURS

Grape FLAVOR

Children's Ibuprofen
Chewable Tablets 100mg
Pain Reliever/Fever Reducer (NSAID)
Chew or crush tablets completely before swallowing

24 Chewable Tablets

REXALL IBUPROFEN
ibuprofen tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-521
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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
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	PURPLE (Lavender)	Score	2 pieces
Shape	ROUND	Size	12mm
Flavor	GRAPE	Imprint Code	L521
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-521-62	1 in 1 CARTON	09/14/2010	
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
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ANDA

ANDA076359

09/14/2010

Labeler - Dolgencorp, LLC (068331990)

Revised: 9/2021

Dolgencorp, LLC