### REXALL IBUPROFEN- ibuprofen tablet, film coated Dolgencorp, LLC

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#### **Dolgencorp, LLC Ibuprofen Tablets 200mg Drug Facts**

#### Active ingredient (in each caplet)

Ibuprofen 200 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

#### **Purpose**

Pain reliever/fever reducer

#### Uses

- temporarily relieves minor aches and pains due to:
- headache
- muscular aches
- minor pain of arthritis
- toothache
- backache
- the common cold
- menstrual cramps
- temporarily 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 chances are higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen,

- or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

#### Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

#### Ask a doctor before use if

- you have problems or serious side effects from taking pain relievers or fever reducers
- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you have asthma
- you are taking a diuretic

#### Ask a doctor or pharmacist before use if you are

- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- 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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

#### Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

#### If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

#### 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**

- do not take more than directed
- the smallest effective dose should be used

adults and children 12 years and older	<ul> <li>take 1 caplet every 4 to 6 hours while symptoms persist</li> <li>if pain or fever does not respond to 1 caplet, 2 caplets may be used</li> <li>do not exceed 6 caplets in 24 hours, unless directed by a doctor</li> </ul>
children under 12 years	• ask a doctor

#### Other information

- read all warnings and directions before use
- store at 20-25°C (68-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)
- see end panel for lot number and expiration date

#### **Inactive ingredients**

colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, iron oxides, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, stearic acid, talc, titanium dioxide

#### **Principal Display Panel**

Ibuprofen Tablets 200mg

Anti-inflammatory

For aches and pains

Pain Reliever/Fever Reducer (NSAID)

actual size

SEE NEW WARNINGS INFORMATION

**GLUTEN FREE** 

\*\*Capsule-shaped tablets





## lbuprofen

Tablets 200mg

SEE NEW WARNINGS INFORMATION





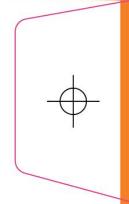
50 Coated Caplets\*\*

#### Drug Facts (continued)

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#### KEEP CARTON FOR REFERENCE

MANUFACTURED FOR DOLGENCORP, LLC 100 MISSION RIDGE GOODLETTSVILLE, TN 37072 USA



# Drug Facts (continued)

If pregnant or breast-leeding, ask a health professional before use, it is especially important not buse buprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may eause problems in the unborn child or complications during delivery.

Keep out of reach of children, in case of overclose, get medical help or contact a Poison Control Center right away.

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#### DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

#### **Drug Facts**

Active ingredient (in each caplet)

Purposes

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■ shock ■ skin reddening ■ rash ■ blisters If an allergic reaction occurs, stop use and seek medical help right away.

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- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
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#### Drug Facts (continued)

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer

right before or after heart surgery

Ask a doctor before use if ■ you have problems or serious side effects from taking pain relievers or fever reducers

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     vomit blood
     have bloody or black stools
  - have stomach pain that does not get better
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- redness or swelling is present in the painful area
- any new symptoms appear







#### REXALL IBUPROFEN

ibuprofen tablet, film coated

#### **Product Information**

Product TypeHUMAN OTC DRUG LABELItem Code (Source)NDC:55910-517

Route of Administration ORAL DEA Schedule

#### **Active Ingredient/Active Moiety**

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Ingredient Name	Basis of Strength	Strength	
IBUPRO FEN (IBUPRO FEN)	IBUPROFEN	200 mg	

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIO XIDE		
STARCH, CORN		
CROSCARMELLOSE SODIUM		
CELLULO SE, MICRO CRYSTALLINE		
POLYETHYLENE GLYCOLS		
POLYVINYL ALCOHOL		
STEARIC ACID		
TALC		
TITANIUM DIO XIDE		

Product Characteristics			
Color	ORANGE	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	I2
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-517-71	1 in 1 CARTON		
1		50 in 1 BOTTLE		

	Marketing Information			
l	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ı	ANDA	ANDA077349	09/06/2012	
ı				

### Labeler - Dolgencorp, LLC (068331990)

Revised: 10/2012 Dolgencorp, LLC