

**BUFFERIN ARTHRITIS- aspirin tablet**  
**Dr. Reddy's Laboratories Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Bufferin Arthritis**

***Drug Facts***

**Active ingredient (in each tablet)**

Buffered aspirin equal to 325 mg aspirin (NSAID)<sup>1</sup> (buffered with magnesium carbonate, calcium carbonate and magnesium oxide)

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<sup>1</sup> nonsteroidal anti-inflammatory drug

**Purpose**

Pain reliever/fever reducer

**Uses**

- temporarily relieves minor aches and pains associated with:
  - headache
  - minor pain of arthritis
  - backache
  - toothache
  - the common cold
  - muscular aches
  - premenstrual & menstrual cramps
- temporarily reduces fever

**Warnings**

**Reye's syndrome**

Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product.

When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert**

Aspirin may cause a severe allergic reaction, which may include:

- hives
- facial swelling
- shock
- asthma (wheezing)

**Stomach bleeding warning**

This product contains an NSAID, which may cause severe stomach bleeding. The chance is 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
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]

**Do not use** if you are allergic to aspirin or any other pain reliever/fever reducer.

**Ask a doctor before use if**

- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have asthma
- you are taking a diuretic

**Ask a doctor or pharmacist before use if you are** taking a prescription drug for

- gout
- diabetes
- arthritis

**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
- an allergic reaction occurs
- symptoms do not improve
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

**If pregnant or breast-feeding**, ask a health professional before use. It is especially important not to use aspirin 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 (1-800-222-1222) right away.

**Directions**

- adults and children 12 years and over: 2 tablets with a full glass of water. Dosage may be repeated every 4 hours while symptoms persist. Do not exceed 12 tablets in 24 hours unless directed by a doctor.
- children under 12 years: do not use unless directed by a doctor

**Other information**

- each tablet contains: **calcium 35 mg** and **magnesium 40 mg**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

**Inactive ingredients**

citric acid, corn starch, dibasic sodium phosphate, hydrogenated vegetable oil, hypromellose, microcrystalline cellulose, polyethylene glycol, propylene glycol, shellac wax, simethicone, sodium lauryl sulfate, talc, titanium dioxide

**Questions or comments?**

**1-800-790-6417**

**PRINCIPAL DISPLAY PANEL - 60 Tablet Bottle Box**



<b>LNK</b> International, Inc. 22 Arkay Drive Hauppauge LI, NY 11788 tel. 631.435.3500 fax 631.952.4680	LNK Part#: B-0385-624-11 DF version: 44-624.03 / 0115 Desc.: Bufferin Arthritis 60 count tablets Size: DG97A Proof #: 3rd UPC: 8 49648 00000 9 NDC/Item: N/A <input type="checkbox"/> Customer: Duocere Pharma Artist: <i>D. Evans</i> Create/Rev. Date: 09/14/11/04_04/04/16	Colors: 	DF Title: 10 pt. Headings: 8 pt. Body Text: 6 pt. Loading: 6.3 pt. Bullets: 5 pt. Barlines: 2 pt. Hairlines: 5 pt.	Horiz. Scale: 80% Bottle Size: 75cc, p/4 IAAA Required Information Most prominent pdp text: 15.81 pt. IAAA active: 9.41 pt. NSAID: 11.13 pt. See new warnings...: N/A	<input type="checkbox"/> Proof Approved <input type="checkbox"/> Approved with Changes <input type="checkbox"/> Reproof Required Adobe® Illustrator CS6
	Drug Facts uses more than 60% of the total surface area. Modified Format used CFR201.66 (d)(10)				

Product Type:  Bottle Only     Clear Bottle     Vial     Tray     Other \_\_\_\_\_  
 (check off all that applies)  Carton & Bottle     Blister Box     5th panel Z-Fold     5th panel Flat Fold

**CUSTOMER IS RESPONSIBLE FOR FINAL PROOF.** This proof has been carefully prepared according to our understanding of our specifications and our OASOP procedures. Keep proof attached to disk. **DO NOT APPROVE THIS PROOF ON GENERAL APPEARANCE.** Please examine it carefully for: 1. Customer specific UPC, product item & NDC numbers 2. Company logo & distribution information 3. Spelling, 4. Spacing, 5. Punctuation/Trademarks, 6. Colors. **We do not assume responsibility for errors and/or omissions after printing.**

**Tough on pain. Gentler to your stomach.**

**BUFFERIN® Arthritis**

**BUFFERED ASPIRIN (NSAID)**

**Pain Reliever/Fever Reducer**

**60 COATED TABLETS**

**325 mg EACH**

**THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN**



<p><b>LNK</b> International, Inc. 22 Arkay Drive Hauppauge LI, NY 11788</p> <p>tel. 631.435.3500 fax 631.952.4680</p>	<p>LNK Part#: L-0385-624-11 DF version: 44-624.03 / 0115 Desc.: Bufferin Arthritis 60 count tablets Size: 1.5 x 5.125 Proof #: 2nd UPC: TBD NDC/Item: TBD Customer: Duocore Pharma Artist: <i>Emma</i> Create/Rev Date: 09/15, 11/13/15</p>	<p><b>Colors:</b></p> <p>Die Line (Do not print) Pantone® 40 Process U RED</p>	<p><b>Die Line</b> <b>Bleed Line</b></p>
	<p>DF Title: 7.5 pt. Headings: 5.5 pt. Body Text: 4.5 pt. Leading: 4.7 pt. Bullets: 3.5 pt. Barlines: N/A Hairlines: N/A</p>	<p>Horz. Scale: 80% Bottle Size: 7566, p004</p> <p>IAAA Required Information Most prominent pdp text: pt. IAAA active: NA NSAID: pt. See new warnings: ... pt.</p>	<p><input type="checkbox"/> Proof Approved <input type="checkbox"/> Approved with Changes <input type="checkbox"/> Reprint Required</p>
<p>Product Type: <input type="checkbox"/> Bottle Only    <input type="checkbox"/> Clear Bottle    <input type="checkbox"/> Vial    <input type="checkbox"/> Tray    <input type="checkbox"/> Other _____  <input checked="" type="checkbox"/> Carton &amp; Bottle    <input type="checkbox"/> Blister Box    <input type="checkbox"/> 5th panel    <input type="checkbox"/> Z-Fold    <input type="checkbox"/> 5th panel    <input type="checkbox"/> Flat Fold _____</p>			
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**BUFFERIN ARTHRITIS**

aspirin tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55741-000
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name		Basis of Strength	Strength	
Aspirin (UNII: R16CO5Y76E) (Aspirin - UNII:R16CO5Y76E)		Aspirin	325 mg	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
citric acid monohydrate (UNII: 2968PHW8QP)				
starch, corn (UNII: O8232NY3SJ)				
Sodium Phosphate, Dibasic (UNII: GR686LBA74)				
hypromelloses (UNII: 3NXW29V3WO)				
cellulose, microcrystalline (UNII: OP1R32D61U)				
Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A)				
propylene glycol (UNII: 6DC9Q167V3)				
sodium lauryl sulfate (UNII: 368GB5141J)				
talc (UNII: 7SEV7J4RIU)				
titanium dioxide (UNII: 15FIX9V2JP)				
<b>Product Characteristics</b>				
Color	WHITE	Score	no score	
Shape	ROUND	Size	11mm	
Flavor		Imprint Code	B	
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55741-000-60	1 in 1 BOX	07/20/2016	
1		60 in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part343	07/20/2016		

**Labeler** - Dr. Reddy's Laboratories Inc. (802315887)

Revised: 12/2019

Dr. Reddy's Laboratories Inc.